

Exhibit

Q

Monday, August 24, 2015 at 4:09:56 PM Central Daylight Time

Subject: RE: 3M/Bair Hugger lawsuit

Date: Monday, March 25, 2013 at 3:17:45 PM Central Daylight Time

From: Welbes, John

To: Scott Augustine

Hi,

OK, I'm working on a story now, suspect it'll be running sometime Tuesday. I'll give you a ring if there are other questions I have. Thanks for all the information.

-- John

From: Scott Augustine [mailto:saugustine@augbiomed.com]
Sent: March 25, 2013 9:54 AM
To: Welbes, John
Subject: Re: 3M/Bair Hugger lawsuit

Dear John,

It occurred to me on reflection that I did not explain why the litigation against 3M that I reported to you on Friday, stands out from the hundreds of other suits that 3M litigates all the time.

Three reasons:

1. These injuries are permanently disabling and have the potential of being very, very large awards—million dollar plus awards. DePuy (J&J) recently lost a hip replacement case for \$8.3 million and those patients just need to get a replacement hip, there is no permanent damage. Also, there were no punitive damages awarded against DePuy.
2. There are a huge number of these injuries compared to most medical device failures. 12,000-20,000 per year in the US alone, depending on whose stats you use.
3. This is a totally new litigation opportunity. Up until now, there have been essentially zero operating room acquired infection lawsuits. This is because it has been impossible to trace the infection to a specific cause with any certainty. Without credible expert testimony as to causation, the lawyers would not even take the case.

The new research that links periprosthetic infections to the waste heat from Bair Hugger warming suddenly changes everything. The experts are saying that if the hospital did everything according to protocol, then the infection most likely came from the waste Bair Hugger heat. This is all it takes to start a whole new huge litigation opportunity. There are tens of thousands of permanently disabled patients who have gone through hell and will very likely jump at the opportunity to sue for their pain and suffering. This is what is known in the business world and "pent up demand."

Additionally, since this is a whole new category of litigation, it has not been planned-for or accrued-for. Not just 3M but also the insurance companies and hospitals.

I hope this helps to explain why the lawsuit that I reported to you on Friday is not just another suit. Please contact me if you have questions.

Sincerely,
Scott

On 3/22/13 4:35 PM, "Scott Augustine" <saugustine@augbiomed.com> wrote:

John,

Page 1 of 3

I sent the info to a couple of others but have not talked to anyone else. I have no idea if there is other interest.
Scott

On 3/22/13 3:52 PM, "Welbes, John" <jwelbes@pioneerpress.com> wrote:

Hi Scott,

Got it. I'm working on a few other things but will start reviewing the attachments now today. Did you pitch this to any other media recently/today?

Thanks much,

John

From: Scott Augustine [mailto:saugustine@augbiomed.com]
Sent: March 22, 2013 3:45 PM
To: Welbes, John
Subject: 3M/Bair Hugger lawsuit

Re: Product liability suit against 3M/Bair Hugger warming

Dear John,

It was very nice chatting with you. What follows is a really interesting story.

A Texas man has sued 3M, claiming that the deep joint infection of his total hip replacement was caused by Bair Hugger (press release and complaint attached). The complaint alleges that Mr. Tommy Walton's hip replacement became infected while being treated with Bair Hugger warming, resulting in permanent disability. After 15 operations spanning the following year, he survived. These patients usually survive, but are almost always permanently disabled, with 12% describing their post-survival life as "worse than death."

In 2010, 3M which now owns Bair Hugger, was fully aware of the evidence that the waste heat from its product caused contamination of the sterile surgical field, posted at www.heat-rises.blogspot.com. About a year ago, a study published in the *Journal of Bone and Joint Surgery* linked Bair Hugger warming to 74% of the catastrophic deep joint infections following total joint replacement surgery. The study by Drs. McGovern and Reed, also corroborated the heat-rises video evidence, proving that the waste heat from Bair Hugger warming contaminates the sterile surgical field with bacteria and other contaminants from the air near the floor (attached).

Since then, four more peer-reviewed studies have been published, further proving the contamination phenomenon (<http://hotdog-usa.com/images/PDFs/US/M206.pdf>). The latest by Drs. Legg and Hamer in the *Bone and Joint Journal* showed that there was over 2,000 times more contaminating particles in the sterile surgical field when Bair Hugger was used compared to air-free HotDog warming—217,300% more (attached)! I am also attaching a manuscript entitled, "Chain of Infection," that puts the entire waste heat linked to deep joint infections issue in context.

3M's response to this research is unfortunate ... they not only failed to warn their customers of this proven risk, but I believe they have actively covered up the problems with deceptive and false marketing. 3M's reckless and irresponsible handling of this matter has exposed hundreds of thousands of surgical patients to needless risk – and created massive liability for the company. In the US alone, there are over 12,000 catastrophic deep joint infections after total joint

Page 2 of 3

replacement surgery per year. Each successful claim, considering defense costs and damages, could easily exceed \$1 million. With a six year statute of limitations in some states, the theoretical liability gets pretty ugly--\$72,000,000,000 and growing year by year if juries decide that punitive damages are warranted for bad corporate behavior.

Of course, not all will sue, but Mr. Walton's case has broken the ice. Others—maybe thousands of others—will follow. The Walton case may be the beginning of the next product liability tsunami which could be big enough to sink 3M.

Thanks for taking the time to talk to me.

Sincerely,
Scott

Scott D. Augustine MD
CEO
Augustine Temperature Management, LLC
Augustine Biomedical + Design, LLC
6581 City West Parkway
Eden Prairie, MN 55344

sauagustine@augbiomed.com
AugustineBiomedical.com
HotDog-USA.com

952-465-3502

Page 3 of 3

Exhibit

R

Redacted

Redacted

Begin forwarded message:

From: HotDog Patient Warming <marketing@augbiomed.com>
Date: August 18, 2016 at 12:14:35 PM EDT
To: <Rhondamont@aol.com>

Subject: CDC Warns Against Blowing Air in the OR

Reply-To: HotDog Patient Warming <marketing@augbiomed.com>

CDC Warns Against Blowing Air in the OR



Dr. Mont,

There is no ambiguity in the information from both the **CDC** and **FDA** regarding air blowing in the operating room.

The **CDC** infection control advisory committee warned:

"[I]t is important not to blow air in the operating theater."¹

"Nothing that blows air should be in an operating theater, if possible."¹

"Until more detailed evidence is available regarding this issue...devices that generate drafts should be banned from the operating room."²

The **FDA**, also investigating infections linked to heater-cooler devices, made an equally strong statement:

"Our investigations have led us to believe that the most likely source of patient infection is through operating room (OR) air"³

Many facilities have discontinued using forced-air warming in orthopedics due to the documented increased risk of peri-prosthetic contamination and concern with over 500 lawsuits brought against 3M/Bair Hugger® by victims of orthopedic implant infections.

Fortunately, there is a patient-warming alternative that does not violate the CDC and FDA recommendation: the HotDog® air-free patient warming system.

Air-free HotDog is the safer solution for orthopedic, cardiac, and neuro surgeries.

HotDog patient warming is:

- air-free
- uniquely versatile: warms from above and below
- more effective
- less expensive

Over 4 million patients have already benefited from HotDog warming. Join your peers and choose the safe, air-free warming solution.

Warm regards,
Scott Augustine MD



For a free cost-savings analysis or to schedule a demo/trial visit
<http://hotdogwarming.com/contact/>

or call 952-465-3500 or toll free 888-439-2767

1. The Healthcare Infection Control Practices Advisory Committee (HICPAC) of the CDC investigating cardiac infections caused by aerosolizing internal contaminants from heater-cooler devices into the operating room air. (Nov 2015)
2. CDC publication: Sommerstien R, Sax H et al. Transmission of *Mycobacterium chimaera* from heater-cooler units during cardiac surgery despite an ultraclean air ventilation system. *Emerging Infectious Diseases Journal 2016; 22(6):1008-1013*
3. Meeting of the FDA's Circulatory Devices panel of the Medical Devices Advisory Committee, also investigating infections linked to heater-cooler devices. (June 2016) page 28, Meeting of the

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Thank you for your interest in updates on infection research.

Our mailing address is:

Augustine Temperature Management
6581 City West Parkway
Eden Prairie, MN 55344

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Exhibit

S

From: Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH)
To: Mark Albrecht
Sent: 2/9/2012 4:36:03 PM
Subject: Re: New Research: ..you may like

Indeed!

From: Mark Albrecht <albre116@umn.edu>

Date: Thu, 9 Feb 2012 15:44:03 +0000

To: Mike Reed <mike.reed@nhs.net>

Subject: Re: New Research: ..you may like

Huh,

I thought those guys at Sheffield might eventually get something out...

On Wed, Feb 8, 2012 at 3:12 PM, Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH) <mike.reed@nhs.net> wrote:

Published today. You might like it!

Bear in mind the Editor of the JBJS is pacing the halls of the Academy – just in case you wanted to print off copies!

BW

Mike

From: Scott Augustine MD <scottaugustinemd@augbiomed.com>

Reply-To: Scott Augustine MD <scottaugustinemd@augbiomed.com>

Date: Tue, 17 Jan 2012 22:46:31 +0000

To: Fax Felton <mike.reed@email.com>

Subject: New Research: Deep Joint Infections Linked to Anesthesia Device



January 17, 2012

Dear Dr. Reed, MBBS MD,

As you prepare to present your research at the Academy meeting, we believe you will want to know more about a study recently published in *JBJS- Br* that relates to your topic.

Research published in the *Journal of Bone and Joint Surgery-Br* (McGovern, Nov 2011) alerted the medical community to a newly found contributor to deep joint infections: forced-air patient warming.

It's been well established that normothermic patients have better outcomes than unwarmed, hypothermic patients. However, the choice of warming methods

has great consequences in orthopedics: forced-air warming devices increase airborne particle counts and have been linked to higher deep-joint infection rates compared to air-free warming devices. In summary:

- **Bair Hugger® contaminates the sterile field** -Waste hot air convection currents transport contaminated air into the surgical site. Conductive fabric warming has no such effect.
- **74% reduction in implant infections**--Orthopedic surgeons significantly reduced deep joint infections after switching to HotDog® conductive fabric warming (1437 patients over 2.5 years, p=0.028).

Researchers concluded: "Air-free warming, therefore, is recommended over forced-air warming for orthopedic procedures." Enclosed is an abstract of this published research. Please let us know if you would like to receive a copy of the complete published study.

As you are well aware, deep joint infections are a disaster for the patient and the hospital. I hope this new information interests you not only as it relates to your research, but also in your medical practice.

Please visit us at the AAOS Annual Meeting at booth #4257 to discuss.

Warm regards,

Scott Augustine MD

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Mark Albrecht
952-261-9903
albre116@umn.edu

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For more information and to find out how you can switch, visit www.connectingforhealth.nhs.uk/nhsmail

Exhibit

T

From: mark albrecht <albre116@gmail.com>
To: taalbrecht@uwalumni.com <taalbrecht@uwalumni.com>
Sent: 5/24/2012 5:53:12 PM
Subject: Hook, line and sinker...

----- Forwarded message -----

From: **Scott Augustine MD** <saugustine@augbiomed.com>
Date: Thu, May 24, 2012 at 11:50 AM
Subject: Re: Further infection data
To: mark albrecht <albre116@gmail.com>

Mark,
How much are you charging for a days work?
Scott

On 5/23/12 8:02 PM, "mark albrecht" <albre116@gmail.com> wrote:

Hi Mike and Scott,
Glad to see that you are still collecting data regarding infection rate differences. Scott forwarded me this email (catch me at albre116@gmail.com from now on). Unfortunately Mike, the question you ask isn't really a quick one. Between data formatting, analysis, and creating a figure/table or two there is at least a full work day involved. I'd be happy to help out if it were only an hour or two, but this is more like a solid day and I'm not on retainer with Augustine for this type of analysis. It would be interesting to incorporate these results into that letter to the editor I drafted for you about 6 months ago. This would, indeed, be a comprehensive data set where you could possibly put to rest the antibiotic control issues that plagued our initial publication.

Maybe you could find a stats guy at your hospital to take a look? I know you had terrible results the last time you tried, but they aren't all bad.

Also, I've attached the abstract I drafted for you about 6-months ago should you want to use that as a starting point. Let me know what you find out.

Regards

-Mark

On Wed, May 23, 2012 at 5:30 PM, Scott Augustine MD <saugustine@augbiomed.com> wrote:

----- Forwarded Message

From: "Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH)" <mike.reed@nhs.net>
Date: Sat, 19 May 2012 07:20:49 +0100
To: Mark Albrecht <malbrecht@augbiomed.com>
Cc: Scott Augustine <saugustine@augbiomed.com>
Conversation: Further infection data
Subject: Re: Further infection data

Mark

I wonder if you could help me out with this? I am keen to know what happened since we looked at this last (old file attached in case you don't have it, and new data) , and also keen to see if we can examine whether the difference is significant comparing 1 Feb 10- 1st June 2010, and what happened since. This is a consistent period without other changes (DVT prophylaxis , antibiotics etc).

Once we have this I can send the letter to the journal...
Mike

From: Mike Reed <mike.reed@nhs.net>
Date: Tuesday, 29 November 2011 11:25
To: Mark Albrecht <albre116@umn.edu>
Cc: Christopher Nachtsheim <nacht001@umn.edu>, "kleland@augbiomed.com" <kleland@augbiomed.com>, Scott Augustine <saugustine@augbiomed.com>
Subject: Re: Hi mike, say the data file you sent me doesn't match the earlier one for overlapping cases...

Mark

Find attached a file that has the dates of diagnosis of infection. The original file I sent for the paper was definitely correct (I checked it multiple times at the time) so just add the ops for new dates from the attached sheet. It was 60 day follow up we used I think, we should stick with that. The question that has been asked by your local team is whether the trend persists and how it effects hips and knees (Ideally need charts and stats).

Your help is much appreciated. I need to get back to them ASAP – but I fully appreciate you have been on it straight away and it is me that has been tardy!

BW
Mike

From: Mark Albrecht <albre116@umn.edu>
Date: Tue, 22 Nov 2011 17:11:26 +0000
To: Mike Reed <mike.reed@nhs.net>
Cc: Christopher Nachtsheim <nacht001@umn.edu>, "kleland@augbiomed.com" <kleland@augbiomed.com>, Scott Augustine <saugustine@augbiomed.com>
Subject: Hi mike, say the data file you sent me doesn't match the earlier one for overlapping cases...

Mike,
I've done a quick analysis of the new data and the trend does persist, but the data files are not totally consistent (in regards to the data the brJBJS article was based upon). I checked the files side-by-side over the common time periods and they do not match up for dates etc.... In fact, in the data file you sent me the infection rate during the forced air warming period was slightly lower than the previous one. Additionally, there is not a date associated with most infections (just a Yes response for about 50% of the infected cases), so clipping at 60 days cannot be done.

So, I'm giving you a graphic for the Wansbeck data, but do not distribute for it "slightly" conflicts with the study data due to different reporting practices in your data. The relevant info supporting the figure is:

Infection ODDS Ratio (FAW,CFW)= 2.98 95%CI (1.36, 6.53)
The p-value for this odds ratio is now=0.0062 (based upon a wald-test)

I'll look at the hip and knee separately next....

--
Mark Albrecht
albre116@gmail.com
952-261-9903

Exhibit

U

From: mark albrecht
To: Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH)
CC: Scott Augustine MD ;Brent Augustine ;Andreas Deibel
Sent: 5/27/2012 7:44:37 PM
Subject: Re: Further infection data

Hi Mike,
Actually, I've always "cut" the transition period out of the data and do not include that portion of data in the analysis. If I should be doing something different, let me know.

In regards to feb 1st 2010, there really isn't enough data after that time period where FAW is in use to do an analysis. Really, you have 1 month of data in the FAW group before you hit the "transition period," which is march 1st 2010. Unfortunately, I won't be able to get anything useful for an analysis with such a short time period and small data set for the FAW group. This is unless the "transition" period really wasn't really a transition period where both FAW and CFW were in concurrent use. If the transition period was FAW only, we might get something useful then because there might be enough cases in the FAW group to run an analysis. This, however, would conflict with the way we presented the data in the brJBJS article.

Please advise regarding the "transition" period and I can finish up the analysis then.

-mark

On Sun, May 27, 2012 at 5:26 AM, Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH) <mike.reed@nhs.net> wrote:
Great. Thank you.

We have always included the transition in the FAW group (I think) as FAW was being used right up to the point I took it away and we put more CFW kit in. The issue about 1 feb 10 is that there were no sig practice changes after that so we can attribute all of that to warming method.
Does that make sense?
The FAW fact article tried to argue it was the other changes which had an effect. They could have some effect (and we said this in our paper). This could put that to bed, or help at least.

Mike

From: mark albrecht <albre116@gmail.com>
Date: Sun, 27 May 2012 00:34:29 +0100
To: Mike Reed <mike.reed@nhs.net>
Cc: Scott Augustine MD <saugustine@augbiomed.com>, Brent Augustine <baugustine@hotdog-usa.com>, Andreas Deibel <adeibel@augbiomed.com>
Subject: Re: Further infection data

Well,

the initial data is looking real good for FAW versus CFW. I've attached the first summary plot (this plot and others will be included in a formal report). Thought you might like a sneak peak at the data.... these differences are highly significant.

Say, I do have a quick question, mike, that you can answer. You wanted to "examine whether the difference is significant comparing 1 Feb 10- 1st June 2010." However, That period was over the "transition" where both FAW and CFW were in use. Could you please re-check those dates for me? That is such a short time-window... I'm wondering if you made a mistake in those dates??? I'll cross-reference the publication too to confirm those dates.

thanks

-Mark

On Sat, May 26, 2012 at 12:50 AM, Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH) <mike.reed@nhs.net> wrote:
Great news. Thank you very much indeed. Mike

From: mark albrecht <albre116@gmail.com>

Date: Fri, 25 May 2012 22:05:54 +0100

To: Scott Augustine MD <saugustine@augbiomed.com>

Cc: Brent Augustine <baugustine@hotdog-usa.com>, Mike Reed <mike.reed@nhs.net>, Andreas Deibel <adeibel@augbiomed.com>

Subject: Re: Further infection data

Ok,

I'll get on it. I'm happy to track time. I think it will take between 4 to 8 hours, depending upon data file inconsistencies and what figures make sense.

-mark

On Fri, May 25, 2012 at 3:59 PM, Scott Augustine MD <saugustine@augbiomed.com> wrote:

Hi Mark,

It doesn't look like very complicated data so I would hope that the full day estimate may be a bit generous and if it doesn't take that long we pay for the actual time spent. Let's go ahead and do some stats on this for Mike so that it can be put into letter to the editor form.

Thanks,

Scott

On 5/24/12 3:10 PM, "mark albrecht" <albre116@gmail.com> wrote:

Hi Scott,

My billable for the analysis and figure generation would be 8 hours @ \$150 an hour (so project total of \$1200). If you want to have me update the "letter to the editor" that would be a couple of additional hours that are not quoted here. Let me know if you are interested. I would have time to do the analysis over the weekend and into the first part of next week.

Best regards,

-Mark

-Mark

On Wed, May 23, 2012 at 5:30 PM, Scott Augustine MD <saugustine@augbiomed.com> wrote:

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From: "Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH)" <mike.reed@nhs.net>

Date: Sat, 19 May 2012 07:20:49 +0100

To: Mark Albrecht <albre116@umn.edu>

Cc: Scott Augustine <saugustine@augbiomed.com>

Conversation: Further infection data

Subject: Re: Further infection data

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Date: Tuesday, 29 November 2011 11:25

To: Mark Albrecht <albre116@umn.edu>

Cc: Christopher Nachtsheim <nacht001@umn.edu>, "kleland@augbiomed.com" <kleland@augbiomed.com>, Scott Augustine <saugustine@augbiomed.com>

Subject: Re: Hi mike, say the data file you sent me doesn't match the earlier one for overlapping cases...

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Your help is much appreciated. I need to get back to them ASAP – but I fully appreciate you have been on it straight away and it is me that has been tardy!

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Mike

From: Mark Albrecht <albre116@umn.edu>

Date: Tue, 22 Nov 2011 17:11:26 +0000

To: Mike Reed <mike.reed@nhs.net>

Cc: Christopher Nachtsheim <nacht001@umn.edu>, "kleland@augbiomed.com" <kleland@augbiomed.com>, Scott Augustine <saugustine@augbiomed.com>

Subject: Hi mike, say the data file you sent me doesn't match the earlier one for overlapping cases...

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The relevant info supporting the figure is:

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The p-value for this odds ratio is now=0.0062 (based upon a wald-test)

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--
Mark Albrecht
albre116@gmail.com
952-261-9903

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Mark Albrecht
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V

From: Scott Augustine <saugustine@augbiomed.com>
To: Mark Albrecht <albre116@gmail.com>
CC: Brent Augustine <baugustine@hotdog-usa.com>;Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST) <mike.reed@nhs.net>;Paul McGovern <pdmcgovern@gmail.com>
Sent: 7/19/2013 11:03:52 PM
Subject: Research

Hi Mark,
I hope your summer is going well.

As you may or may not know, we have have pretty regular (though lame) critique of Paul and Mike's paper saying that the change in antibiotic regime part way through the BH group makes the whole thing invalid. While that may be grasping at straws for 3M through Parvizi or ECRI trying to look smart, I think that we can fix it pretty easily. What I would like to do is to redo the stats eliminating the period of the first antibiotic.

Since there are 7 months of HD patients 6/1/10- 1/1/11, we take the same number of months of BH patients 8/1/09-3/1/10. We leave the "transition" period the same. The other advantage of the 8/1/09 start date is that is the start date for the rivaroxaban thromboprophylaxis which ended during the "transition" period. Therefore we have a BH treated group that got all the same antibiotics and thromboprophylaxis and a HD treated group that got all the same antibiotics and thromboprophylaxis. However the BH and HD groups got different thromboprophylaxis. While the total number of patients will be much smaller, it should still be more than 700 and eyeballing the data on p1543, I think the results will be even more compelling.

We will have to argue that the infection improvement is not due to the thromboprophylaxis but I think that is a lot easier to argue than changing antibiotic regimes. I know that we can't re-publish this but we can put it out as a white paper and/or maybe Mike or Paul would want to write a letter to the editor.

My question is; do you still have the raw data and if so, how long (and how much would it cost) to have you recalculate the stats? If you don't have the necessary raw data, can Mike send it to you?

All the best,
Scott

Exhibit

W

From: mark albrecht
To: 'Scott Augustine'
Sent: 7/22/2013 4:50:18 AM
Subject: RE: Research

Hi Scott,

I should have the data if it is the prior data Mike sent me. The question is do you want me to re-do the analysis given mike's comments? I would have time the week of August 5-9th (I've got a regular consulting contract with CH Robinson that wouldn't let me get to this job till that date and I'm out on vacation the week following this one). Also, I'm hoping that the results will come out significant with "fewer" data points, but from the looks of the graph this is likely to be the case as you mention. Also, if you want me to re-do the analysis Mike may have more data to add to the right hand side of the graph (more hot-dog data). Might be of interest given that you are considering having the stats re-done... Just a thought.

Regarding costs, I'd imagine that this would take about 1 day since I would have to re-review the data, review the old stats code, write some new stats code, make a couple of figures, and document the results. The standard rate I charge for 1-day engagements is \$200/hr. So this would be about \$1,600 for the whole package + write-up.

Let me know your thoughts and whether this is still of interest to you.

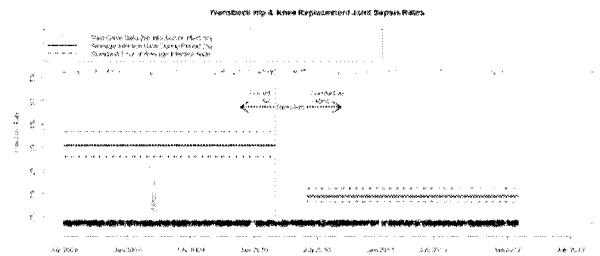
Best
-Mark

From: Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST) [mailto:mike.reed@nhs.net]
Sent: Friday, July 19, 2013 11:48 PM
To: Scott Augustine; Mark Albrecht
Cc: Brent Augustine; Paul McGovern
Subject: Re: Research

I think I sent further raw data last year just before my US tour and Mark made a slide.

I did see the critique that Parvizi wrote about our paper and for my talk a couple of weeks ago I did add this arrow to the slide, and explained it in my talk – but his flight was late..

Clinical results of swap



I don't have a great appetite for writing to the editor though – I think there is probably enough background concern so it is reaching peoples consciousness. What we need here is an RCT.

Mike

From: Scott Augustine <saugustine@augbiomed.com>
Date: Friday, 19 July 2013 23:03
To: Mark Albrecht <albre116@gmail.com>
Cc: Brent Augustine <baugustine@hotdog-usa.com>, Mike Reed <mike.reed@nhs.net>, Paul McGovern <pdmcgovern@gmail.com>
Subject: Research

Hi Mark,
I hope your summer is going well.

As you may or may not know, we have have pretty regular (though lame) critique of Paul and Mike's paper saying that the change in antibiotic regime part way through the BH group makes the whole thing invalid. While that may be grasping at straws for 3M through Parvizi or ECRI trying to look smart, I think that we can fix it pretty easily. What I would like to do is redo the stats eliminating the period of the first antibiotic.

Since there are 7 months of HD patients 6/1/10- 1/1/11, we take the same number of months of BH patients 8/1/09- 3/1/10. We leave the "transition" period the same. The other advantage of the 8/1/09 start date is that is the start date for the rivaroxaban thromboprophylaxis which ended during the "transition" period. Therefore we have a BH treated group that got all the same antibiotics and thromboprophylaxis and a HD treated group that got all the same antibiotics and thromboprophylaxis. However the BH and HD groups got different thromboprophylaxis. While the total number of patients will be much smaller, it should still be more than 700 and eyeballing the data on p1543, I think the results will be even more compelling.

We will have to argue that the infection improvement is not due to the thromboprophylaxis but I think that is a lot easier to argue than changing antibiotic regimes. I know that we can't re-publish this but we can put it out as a white paper and/or maybe Mike or Paul would want to write a letter to the editor.

My question is; do you still have the raw data and if so, how long (and how much would it cost) to have you recalculate the stats? If you don't have the necessary raw data, can Mike send it to you?

All the best,
Scott

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NHSmail provides an email address for your career in the NHS and can be accessed anywhere

Exhibit

X

From: Mark Albrecht <albre116@gmail.com>
To: Scott Augustine <saugustine@augbiomed.com>
CC: Andreas Deibel <adeibel@augbiomed.com>
Sent: 7/19/2016 3:56:09 AM
Subject: I've been subpoenaed by 3M's lawyers for MDL 2666

Hi Scott (and AD),

we cross paths again. So, 3M was kind enough to send a dead drop guy to my work office today to serve me a subpoena (all of about 90 pages). Looks like you are having some litigation success (I had no clue), but the subpoena requests 2 things from me, one of which is not a small thing...:

- 1) a personal deposition, which I'll handle and am fine with and;
- 2) a huge cache of documents related to the research we published (there were about 40 line items requested in an exhaustive manner). I'm happy to share the subpoena with you.

In regards to #2, I might need some help getting those files. You have them all at the company and, as you know, all of our research was well designed/documents so we should produce them in full. Plus, there is the email trail with pace labs microbe culturing discussions we want to capture, along with our independent rating of the filters by the aerosol lab in eden praries. I think I have the bulk of the files on that old laptop I have from you guys, but I'm not sure I can remember the password and we might need to have an admin unlock it. I'll give it a go tomorrow and let you know.

So, lets touch base here if you can/are willing to.

best

-m

--

Mark Albrecht
albre116@gmail.com
952-261-9903

Exhibit

Y



Christopher Nachtsheim <nacht001@umn.edu>

Conference call to discuss 1st manuscript: Laminar flow disruption

4 messages

Mark <malbrecht@augbiomed.com> Wed, Mar 31, 2010 at 11:26 AM
 To: Scott Augustine <saugustine@augbiomed.com>, Andreas Deibel <adeibel@augbiomed.com>, Tom Neils <tneils@augbiomed.com>
 Cc: robinhumble29@gmail.com, Mr Mike Reed <mike.reed@nhs.net>, Chris Nachtsheim <nacht001@umn.edu>, Randy Benham <rbenham@augbiomed.com>

Scott, Andreas, and Tom,
 Robin has organized a 11am phone conference to discuss the laminar flow disruption study manuscript with Mike Reed. If you can participate, that would be great. I'll be calling in from the U of M with Chris. See the phone number below for the call in.

Thanks
 -mark

-----Original Message-----

From: Robin Humble [mailto:robinhumble29@googlemail.com]
 Sent: Wednesday, March 31, 2010 11:22 AM
 To: 'Mark'
 Cc: 'Chris Nachtsheim'
 Subject: RE: Conversation last week

Mark this is the dial in at 5pm UK time

+44 844 873 60 60
 Pass key 56059

Please pass this on to anyone else from the US who plans to join the call, including Scott, AD etc..

Robin Humble

+44 7802 662727 (Mobile)

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-----Original Message-----

From: Mark [mailto:malbrecht@augbiomed.com]
 Sent: 31 March 2010 16:35

To: robinhumble29@gmail.com
Cc: 'Chris Nachtsheim'
Subject: RE: Conversation last week

That will be fine on friday. I will need to call in from the University of Minnesota. I will be in a meeting with my phd advisor, but he is a part of the current manuscript and I'm sure would like to join in on the call.

Let me know what number to call
-mark

-----Original Message-----

From: robinhumble29@googlemail.com [mailto:robinhumble29@googlemail.com]
Sent: Wednesday, March 31, 2010 4:42 AM
To: Mr Mike Reed; Mark Albrecht; Scott Augustine
Cc: Randy Benham; Andreas Deibel
Subject: Re: Conversation last week

Mark
How does 5pm UK time, 11am Minn. work.
Robin
Sent using BlackBerryR from Orange

-----Original Message-----

From: "Reed Mike (Northumbria Health Care NHS Trust)" <mike.reed@nhs.net>
Date: Wed, 31 Mar 2010 09:40:57
To: robinhumble29@gmail.com<robinhumble29@gmail.com>; Mark
Albrecht<malbrecht@augbiomed.com>; Scott Augustine<saugustine@augbiomed.com>
Cc: Randy Benham<rbenham@augbiomed.com>; Andreas
Deibel<adeibel@augbiomed.com>
Subject: RE: Conversation last week

5-6 best for me. I have a 6 pm meeting.

-----Original Message-----

From: robinhumble29@googlemail.com [mailto:robinhumble29@googlemail.com]
Sent: 31 March 2010 09:33
To: Reed Mike (Northumbria Health Care NHS Trust); Mark Albrecht; Scott
Augustine
Cc: Randy Benham; Andreas Deibel
Subject: Re: Conversation last week

Its good for me Mike, it would probably be best for the team in the US, if we could make this after 5pm, how does that sound?

Regards
Robin

Sent using BlackBerry(r) from Orange

-----Original Message-----

From: "Reed Mike (Northumbria Health Care NHS Trust)" <mike.reed@nhs.net>
Date: Wed, 31 Mar 2010 06:07:52
To: Mark<malbrecht@augbiomed.com>;
robinhumble29@gmail.com<robinhumble29@gmail.com>; 'Scott
Augustine'<saugustine@augbiomed.com>
Cc: 'Randy Benham'<rbenham@augbiomed.com>; 'Andreas
Deibel'<adeibel@augbiomed.com>

Subject: RE: Conversation last week

Unfortunately I have a three session days this week and my trainee is away (who normally does all the work!).

I could probably have a telecon at 5pm UK time on Thursday but Friday is strangely much more convenient as it is a holiday - I can read/review the paper and have time to discuss it properly. Is anyone able to meet Friday afternoon UK time?

Mike

-----Original Message-----

From: Mark [mailto:malbrecht@augbiomed.com]
 Sent: 30 March 2010 17:09
 To: robinhumble29@gmail.com; 'Scott Augustine'; Reed Mike (Northumbria Health Care NHS Trust)
 Cc: 'Randy Benham'; 'Andreas Deibel'
 Subject: RE: Conversation last week

Ok, how about this. Lets use a Thursday meeting to review, with mike, the current laminar flow manuscript and answer any questions/concerns he may have. Then, let's set up a second meeting for Monday or Tuesday to cover a drafted protocol that should be completed by then.

What do you think?

-----Original Message-----

From: robinhumble29@googlemail.com [mailto:robinhumble29@googlemail.com]
 Sent: Tuesday, March 30, 2010 11:01 AM
 To: Mark Albrecht; Scott Augustine; Mr Mike Reed
 Cc: Randy Benham; Andreas Deibel
 Subject: Re: Conversation last week

Mark

This is great, remember that we use a different voltage on devices, we may need a transformer to use a 110 volt machine as we use 210/220 Its a Holiday here Friday, what about Thursday?

Regards

Robin

Sent using BlackBerryR from Orange

-----Original Message-----

From: "Mark" <malbrecht@augbiomed.com>
 Date: Tue, 30 Mar 2010 10:40:02
 To: <robinhumble29@gmail.com>; 'Scott Augustine'<saugustine@augbiomed.com>; 'Reed Mike (Northumbria Health Care NHS Trust)'<mike.reed@nhs.net>
 Cc: 'Randy Benham'<rbenham@augbiomed.com>; Andreas Deibel<adeibel@augbiomed.com>
 Subject: RE: Conversation last week

Robin,

I'm planning on sending Andreas that week to assist you in the data collection and provide help following a drafted protocol. We are working to create the sampling protocol draft for you and mike to review and add input to this week. We will also be providing a particle tracer generator and the bubble machine (should have it by then). I've been in our flow lab the last couple of days getting things de-risked. A conference call would be great.

Propose a time. I'd suggest late this week for I could have a protocol together by then.

-mark

-----Original Message-----

From: Robin Humble [mailto:robinhumble29@googlemail.com]
 Sent: Tuesday, March 30, 2010 10:28 AM
 To: 'Scott Augustine'; 'Reed Mike (Northumbria Health Care NHS Trust)';
 'Mark'
 Cc: 'Randy Benham'
 Subject: FW: Conversation last week

Dear Mike,

Please see confirmation from Mary at Vanguard regarding access to their Laminar Flow theatre April 24th and 25th.

I think we need to start to put together everything that we will need for the weekend, including Bair Huggers ect. How would you like to manage this, I have copied Scott and Mark Albrecht in the US to see what help they can give us, perhaps we should organise a conference call regarding this.

Please let me know if you have any questions.

Regards

Robin

Robin Humble

+44 7802 662727 (Mobile)

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-----Original Message-----

From: Mary Smallbone [mailto:MarySmallbone@vanguardhealthcare.co.uk]
 Sent: 30 March 2010 16:13
 To: 'robinhumble29@gmail.com'
 Subject: Re: Conversation last week

Hi Robin

Thank you for your email and voice message I hope you are feeling better

We are planning to use Ipswich as the venue I have organised for Scott Horsley - senior theatre manager and Ian Balaam - maintenance engineer to be

present they will open and close the unit and also they will be able to alter the temperature and air flows if required

The address of where the unit is

PCT Treatment Centre

Walker Close

Ipswich

Suffolk

IP3 8LY

We will be charging you as discussed so please can you let me know who you want who and where to send the invoice to

I will send an email to Scott and Ian following this one so that they can answer your laminar flow questions

Best wishes

Mary
Mary Smallbone
Sales and Operations Director

t: 01452 651882
m: 07771 851913

www.vanguardhealthcare.co.uk
Vanguard Healthcare Solutions Ltd.
Unit 1411 Charlton Court
Gloucester Business Park
Gloucester GL3 4AE

----- Original Message -----

From: Robin Humble <robinhumble29@googlemail.com>
To: Mary Smallbone
Sent: Tue Mar 30 09:52:14 2010
Subject: Conversation last week

Hi Mary,

Sorry I missed your call on Friday, in fact I have been laid low with some type of virus, but am back today and would like to continue our conversation regarding the Mobile Theatre in Ipswich. The days that I have provisionally booked in my diary are the 24/25th April, are these still good for you?

It would help us if we could obtain some specs regarding the Laminar flow in the theatre we will be using in order to be able to work up some of our

calculations. I think that there will be three or four of us working on that weekend, one, Mike Reed is a Consultant Orthopaedic Surgeon from Northumbria, the other Professor Leaper from UHL, one of our Research technicians and myself.

You mentioned that you would have a couple of technicians on site, is that still the case, it would really help us, of course we will pay whatever we need to.

If it helps to talk by phone please let me know when this is convenient and I can call, assuming your number is still 07771 851913.

Warm regards

Robin

Robin Humble

+44 7525 226284 (Mobile)

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Robin Humble

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www.connectingforhealth.nhs.uk/nhsmail

Mark <malbrecht@augbiomed.com>

Wed, Mar 31, 2010 at 11:39 AM

To: Mark <malbrecht@augbiomed.com>, Scott Augustine <saugustine@augbiomed.com>, Andreas Deibel

<adeibel@augbiomed.com>, Tom Neils <tneils@augbiomed.com>

Cc: robinhumble29@gmail.com, Mr Mike Reed <mike.reed@nhs.net>, Chris Nachtsheim <nacht001@umn.edu>, Randy Benham <rbenham@augbiomed.com>

I also suppose I should attach the manuscript we will be discussing during the call. Mike, this is the same version I sent you earlier.

Thanks

-mark

[Quoted text hidden]

 [Manuscript_Laminar_Draft_1.doc](#)
301K

Mark <malbrecht@augbiomed.com>

Wed, Mar 31, 2010 at 4:14 PM

To: Andreas Deibel <adeibel@augbiomed.com>

Cc: Scott Augustine <saugustine@augbiomed.com>, Randy Benham <rbenham@augbiomed.com>, Tom Neils

<tneils@augbiomed.com>, Chris Nachtsheim <nacht001@umn.edu>, "Reed Mike (Northumbria Health Care NHS Trust)" <mike.reed@nhs.net>, robinhumble29@gmail.com

Phone call date changed to Thursday 5pm based upon Robin and Mike's availability. Same phone in instructions. Chris, I can get you up to speed during our Friday meeting or you can call in and participate--- your choice.

-mark

-----Original Message-----

From: Andreas Deibel [mailto:adeibel@augbiomed.com]

Sent: Wednesday, March 31, 2010 4:08 PM

To: 'Mark'

Subject: RE: Conference call to discuss 1st manuscript: Laminar flow disruption

I'll be there

Andreas Deibel
Hot Dog International
Augustine Biomedical + Design
6581 City West Pky
Eden Prairie, MN 55344
952-465-3520
952-456-2240 cell
952-465-3501 fax
adeibel@augbiomed.com

-----Original Message-----

From: Mark [mailto:malbrecht@augbiomed.com]
Sent: Wednesday, March 31, 2010 11:26
To: 'Scott Augustine'; 'Andreas Deibel'; 'Tom Neils'
Cc: robinhumble29@gmail.com; 'Mr Mike Reed'; 'Chris Nachtsheim'; 'Randy Benham'
Subject: Conference call to discuss 1st manuscript: Laminar flow disruption

[Quoted text hidden]

Robin Humble <robinhumble29@googlemail.com>

Thu, Apr 1, 2010 at 8:38 AM

Reply-To: robinhumble29@gmail.com

To: Mark <malbrecht@augbiomed.com>, Andreas Deibel <adeibel@augbiomed.com>
Cc: Scott Augustine <saugustine@augbiomed.com>, Randy Benham <rbenham@augbiomed.com>, Tom Neils <tneils@augbiomed.com>, Chris Nachtsheim <nacht001@umn.edu>, "Reed Mike (Northumbria Health Care NHS Trust)" <mike.reed@nhs.net>

Mark,

Lets still use the dial-in number that I passed around yesterday.

Thanks

Robin

Robin Humble

+44 7802 662727 (Mobile)

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-----Original Message-----

[Quoted text hidden]

Exhibit

Z

Forced Air Warming versus Conductive Fabric Blankets – An Evaluation of Laminar Flow Disruption

Mike Reed, MD
(Add info and affiliation of 1st author)

Scott Augustine, MD
Chief Executive Officer
Augustine Biomedical + Design
Eden Prairie, Minnesota, USA

Mark Albrecht, BSME, MBA
Clinical Research Manager
Augustine Biomedical + Design
Eden Prairie, Minnesota, USA

Christopher Nachtsheim, PhD
Carlson School of Management
University of Minnesota
Minneapolis, Minnesota, USA

David Leaper MD ChM FRCS FACS
Visiting Professor
Department of Wound Healing
Cardiff University
Cardiff CF14 4XN, UK

Correspondence to: malbrecht@augbiomed.com

Key words: surgical site infection, forced air warming, laminar air flow, operating room environmental contamination, operating room ventilation

Abstract

Introduction: Operating room laminar ventilation is designed to protect the surgical site from airborne pathogenic contaminants. Laminar ventilation performance is fragile in nature and can be compromised by flow obstructions (personnel) and thermals (heated air). Patient warming systems, used to prevent surgical hypothermia, represent a potential source of ventilation disruption via the waste heat they generate. Thus, we sought to compare the effects of two patient warming modalities classified as having “low waste heat load” (conductive fabric blanket) and “high waste heat load” (forced air warming) on operating room ventilation performance.

Methods: In a laminar flow ventilation laboratory with 0.3 m/s airflow, a mannequin was draped for an abdominal incision. Tobacco smoke particulate was introduced at floor level under the operating table as a tracer. Laminar ventilation performance was assessed by determining the amount of tracer detected 6 inches above the surgical site. Each patient warming device (lower body blanket/coverlet) was tested with and without the presence of a surgeon standing next to the operating table.

Results: Forced air warming use on high heat resulted in a significant increase in the percentage of tracer laden air from under the operating table detected at the surgical site versus control for experiments without a surgeon (+2.7%, ***P<0.05***) and with a surgeon (+42.4%, ***P<0.01***). In contrast, conductive fabric blankets on high heat resulted in no significant increase in the percentage of tracer laden air detected at the surgical site versus control for experiments without a surgeon (-0.1%) or with a surgeon (-1.3%).

Conclusion: The use of forced air warming was found to generate sufficient waste heat to disrupt laminar ventilation performance and mobilize tracer contaminated air under the table upwards into the surgical site. These effects were magnified with the presence of a surgeon where his/her legs and torso acted as a flow stabilizing boundary that the heated air could rise against. In contrast, conductive fabric blankets did not generate sufficient waste heat to affect laminar ventilation performance.

Introduction

Operating room (OR) ventilation plays a critical role in preventing surgical site infection (SSI) by protecting the operative site from microbial-laden dust, lint, skin squames, and respiratory droplets resident in OR air¹⁻⁷. OR ventilation systems are classified as either conventional or laminar based upon their design: conventional systems supply a turbulent airflow filtered to an efficiency of $\geq 90\%$ ⁸; laminar systems direct a uniform velocity airflow (0.3 to 0.5 m/s) over the surgical site filtered to an efficiency of $\geq 99.97\%$ to sweep away contaminants⁹. Laminar ventilation offers added protection from airborne contaminants and is typically utilized for contamination sensitive operations, such as the implantation of prosthetics¹⁰. Recent research has challenged the use of forced air warming (FAW) in such laminar environments due to the risks of FAW generated contaminants reaching the surgical site via the vented waste airflow¹¹⁻¹⁵. However, these studies focused on solely quantifying contaminants in the direct air effluent from FAW blowers and did not consider a second, but equally important source of SSI risk: the disruption of OR laminar airflow due to vented waste heat from FAW devices.

Laminar airflows are fragile in nature and highly sensitive to flow obstructions (surgical lights, people, etc...) and movements of the surgical staff^{16,17}, both of which create regions of turbulence in the uniform airflow that draw contaminants into the surgical site. Adequate laminar flow velocity has been identified as the critical factor for lessening the impacts of these factors on ventilation performance¹⁸. However, even moderately heated air from surgical equipment and lamps has sufficient buoyancy to greatly reduce the downward velocity of the laminar flow in a localized region.

The vented waste heat emitted from FAW blowers is a far greater source of thermal energy in the laminar flow field than nearly all commonly used OR equipment. The heated airflow from FAW blowers is released at 43°C, which is often 20°C above ambient OR conditions, and can contribute upwards of 800 watts of vented waste heat in close proximity to the surgical site^{19,20}. The release of such thermal energy has the potential to generate temperature gradients that impede the performance of the laminar

flow ventilation system. Further, the release of FAW vented waste heat is often directed towards the floor into resident air that is potentially contaminated with shed skin cells and respiratory droplets. Provided that the vented waste heat is sufficiently buoyant, it may be possible for it to mobilize contaminated resident floor air towards the surgical site against the downward velocity of the laminar flow. Supporting evidence for this phenomenon can be seen in a recent research video that captures the effects of forced air warming waste heat generated air currents on OR ventilation performance²¹.

Air-free alternatives, such as conductive fabric blankets, have been developed that are comparably effective to FAW for the prevention of surgical hypothermia²²⁻²⁸. With the availability of such alternatives, there is a need to critically assess the impact of FAW versus air-free alternatives on laminar flow ventilation performance. Thus, we studied the effects of FAW versus conductive fabric warming on ventilation performance in a laminar flow laboratory representative of an OR environment.

This study was designed to:

- (i) Compare the effects of waste heat from either FAW or conductive fabric blanket use on OR ventilation performance in:
 - 1) an OR environment having no surgical staff; and
 - 2) an OR environment having a single surgeon standing in the laminar flow field.
- (ii) Determine whether sufficient waste heat is generated to mobilize resident floor air towards the surgical site with either FAW or conductive fabric blanket use.

Methods

Laminar Flow Laboratory Setup

A laminar flow OR laboratory was constructed (**Fig 1**) with a HVAC ventilation blower that provided a pressurized airflow to a ceiling plenum. The downstream surface of the plenum was lined with a point of use HEPA filtration media (Technostat, Hollingsworth and Vose, East Walpole, MA) that acted as a diffuser to create a downward laminar flow over the operating table with a uniform velocity of 0.3 m/s, as measured 50 cm downstream of the HEPA filter. The HEPA filtered air exited the laboratory through a series of 8 return grates (20 by 40 cm) located 30 cm from the floor, with 2 return grates per each of the 4 walls. When in operation, the laboratory created a downward laminar airflow region having a cross section of 2.4 by 2.4 meters and a positive pressure of 0.4 cm H₂O inside the room.

In the center of this laminar airflow region, a mannequin was laid in a supine position on the operating table and draped in accordance with standard operating procedures for an abdominal incision (**Fig 2**). Draping consisted of laying a full body surgical drape with no surgical site opening across the mannequin, with the sides of the drape hanging downwards and terminating 50 cm off of the floor. At the head of the table, the drape was tented to create an ether screen for anesthesia access. The experimental warming treatment was slid under the drape and applied to the mannequin and was either: 1) a lower body FAW coverlet (Bair Hugger Model 525, Arizant Healthcare, Eden Prairie, MN); or 2) a conductive fabric blanket (Hot Dog Model B103, Augustine Biomedical + Design, Eden Prairie, MN). The conductive fabric blanket turned “off” served as the control. An aerosolized tobacco smoke tracer was created outside the laboratory and delivered to the space under the operating table by means of a blower and hose delivering 0.028 m³ per minute of airflow. The hose was made sufficiently long to ensure that the particulate tracer had cooled and thermally equilibrated with the environment before introduction.

The conductive fabric blanket treatment was powered by a standard controller (Model WC02, Augustine Biomedical + Design). The FAW coverlet was powered by a FAW blower (Model 750, Arizant Healthcare) modified to have an in-line hose filter. The in-line hose filter was constructed of an electrostatic HEPA filtration media (Technostat, Hollingsworth & Vose) having a cross-sectional area of approximately 625 cm², which did not materially affect the airflow delivered to the FAW coverlet. The temperature of the air exiting the FAW blower is controlled by the distal hose end sensor downstream of the inline hose filter. Therefore, the in-line filter did not alter the temperature of the airflow delivered to the FAW coverlet.

Experimental Design

The experiment involved a full factorial design assessing changes in tracer particle concentration above the surgical site due to the effect of three 2-level factors defined as: 1) surgeon present or absent, with present defined as a gowned person standing next to the surgical site performing repeated hand movements over the mannequin's abdomen but not touching anything; 2) patient warming modality, having the levels of FAW coverlet and conductive fabric warming; and, 3) controller heat setting, having the levels of heater "off" (called "ambient" for FAW) and heater "on" high heat (43°C).

At the beginning of each day, laminar flow ventilation uniformity and tracer particle concentrations under the operating table were recorded. FAW blower distal airflow particle concentrations were measured during day 3 of testing. For each treatment combination, tracer particle concentrations above the operating site were recorded via particle counting as described above.

Sampling Procedures

Measurements were made in the laminar flow laboratory over the course of 3 days to quantify:

- (i) Laminar ventilation flow uniformity, which was recorded using a hot wire anemometer (Model HHF42, Omega Engineering, Stamford, CT) that reported both

temperature and air flow. Measurements of airflow and temperature were taken 50 cm below the ventilation air delivery plenum in the center and four corners (30 cm diagonally inward from the corners of the ventilation plenum structure).

(ii) Tracer particle concentrations, which were measured: 1) “under the operating table” - defined as 50 cm off the floor under the operating table and between the lower edges of the surgical drape; 2) “above the surgical site” - defined as 15 cm above the abdomen of the draped mannequin; and 3) “within the FAW blower distal airflow” - defined as the core of the airflow 2 cm past the distal hose exit. Particle concentrations were recorded using a laser particle counter (Handilaz Mini, Particle Measuring Systems, Boulder, CO). For each measurement, five 0.028 m³ particle counts were taken in sequential order.

Assessments

Tracer penetration of the laminar flow was calculated as the ratio of average particle concentration 15 cm above the surgical site to average particle concentration 50 cm off the floor under the operating table for each experiment. A pooled under table average across all experiments was selected as the denominator because pilot research showed under table tracer concentrations to be stable and consistent.

Tracer penetration of the laminar flow indicates the degree to which tracer-laden under-table air is being mobilized upwards into the surgical site against the downward laminar airflow current. Values represent the percent mixture of the air in the region above the surgical site originating from under the operating table.

Statistical Analysis

A variance weighted ANOVA model was fitted to the tracer penetration of the laminar flow data with the following 2-level fixed effects: 1) surgeon (present or absent); 2) warming modality (FAW or conductive fabric); and, 3) controller heat setting (“off” or “on”). Additionally, all second and third level interactions were included in the analysis. Pair wise differences were computed between treatment effects at the same surgeon level, thus, 2 sets of comparisons were formed: one for the set of experiments with no surgeon present and another for the set of experiments having a surgeon present. Reported

P*v*alues are 2-tailed and Bonferroni family wise error rates were applied jointly to all pair wise comparisons for determination of significance.

Results

A total of 8 experimental runs were performed representing the 8 treatment combinations identified by the experimental design (**Fig 3**). Temperature and air velocity measurements confirmed a stable and uniform laminar flow environment, which had a temperature ranging from 21.0 to 21.5 °C and an air velocity of 0.3 m/s over the course of experiments. A pooled under-table tracer particle concentration average of 52,398 particles $\geq 0.3 \mu\text{m}/\text{m}^3$ was used as the denominator in all calculations. The variation in under-table tracer particle concentration was small compared to the magnitude of observed treatment effects.

Measurements of airflow exiting the FAW blower showed tracer particle concentrations to be 0.4% of those in under-table air. This reduction indicates that the added in-line hose filter was very effective at removing tracer particulate from the airflow supplied to the FAW coverlet. Thus, any tracer particle detected at the surgical site is not likely to have passed through the FAW blower.

Tracer Penetration of the Laminar Flow

All ANOVA model main effects and interactions were found to be significant (**Table 2**). As such, the effects of experimental factors on tracer penetration of the laminar flow must be considered jointly. For experiments performed without a surgeon, pair wise differences were not significant between the treatments of conductive fabric “heat off” (control)- 0.4%, conductive fabric “heat on”- 0.3%, and FAW “ambient”- 0.3%. These experimental treatments were characterized as contributing “minimal or no waste heat” and had a similar effect on laminar ventilation performance. The use of FAW on “heat on” added a “waste heat” load to the system, and under the same conditions (no surgeon) was found to moderately elevate tracer penetration of the laminar flow to 3.1% ($P<0.05$).

The addition of a surgeon, simply standing next to the operating table, led to a moderate elevation in tracer penetration of the laminar flow for treatments having “minimal or no waste heat” (conductive fabric “heat off” (control)- 6.2%, conductive fabric “heat on”- 4.9%, and FAW “ambient”- 7.1%). Again, non-significant pair wise differences indicate that these treatments had a similar effect on laminar ventilation performance in the presence of a surgeon. For treatments having a “waste heat” load, the presence of a surgeon greatly increased tracer penetration of the laminar flow (FAW “heat on”- 48.6%). Compared to treatments having “minimal or no waste heat”, the use of FAW on “high heat” in the presence of a surgeon resulted in an approximately 10-fold increase in the quantity of under-table tracer-laden air reaching the surgical site ($p<0.01$).

Discussion

This is the first study to assess the impact of two different patient warming modalities, FAW and conductive fabric heating blankets, on laminar ventilation performance in an OR environment. The results of this study suggest that the use of FAW can generate sufficient vented waste heat to disrupt the laminar flow ventilation protecting the surgical site from airborne contaminants. Further, the adverse effects of FAW vented waste heat were found to be exponentially magnified when a surgeon stands by the operating table in the laminar flow field. In contrast, the use of conductive fabric warming was shown to have no effect on the laminar flow in the vicinity of the surgical site. The results also showed that the waste heat from FAW use, when vented near the floor, has the ability to convey resident air into the surgical site from high risk areas, such as under the operative table.

We felt it was important to perform the experiment using a FAW lower body blanket to ensure that airflow exiting the coverlet was vented downwards and away from the surgical site. Thus, any tracer particles reaching the surgical site would be due to upward air currents originating from under the operating table. Further, tracer particles were cooled to room temperature before introduction under the operating table to assure that they did not contribute to the “waste heat” load. Particle counting demonstrated that the stability of the laminar flow environment in the vicinity of the surgical site was

unaffected by the use of conductive fabric blankets in the heat “on” or “off” condition. The laminar flow was also unaffected by FAW in the heat “ambient” condition. For those conditions classified as having “minimal or no waste heat”, the laminar flow system was effective for protecting the surgical site from under-table tracer particles.

In contrast, the use of FAW with heat “on” was found to greatly impact the stability of the laminar flow environment. Simply turning the FAW heat “on” resulted in roughly a 10-fold elevation in the number of tracer particles detected above the surgical site when compared to treatments having “minimal or no waste heat.” OR environments are normally maintained in the range of 20-25°C, meaning that the vented waste heat from FAW can be as much as 10°C in excess of the ambient environment. Such temperature differences impart a natural buoyancy to the vented FAW waste air that causes it to rise upwards towards the surgical site. In our study, the waste air and heat from FAW use accumulated under the tent formed by the operating table and the lower edge of the surgical drape. The heated air then escaped from under the lower edge of the drape and appeared to rise along the sides of the operating table towards the surgical site

The ability of the vented waste heat to rise against the downward laminar flow was found to be highly dependent on whether a surgeon was present in the environment. The presence of a surgeon has two distinct effects on the stability of the laminar flow environment. First, independent of patient warming, the surgeon’s body physically disrupts the downward laminar flow field and creates a turbulent wake that extends outward in the profile of an expanding cone²⁹. This “wake” effect is the most plausible explanation as to why tracer particle counts were found to be equally elevated for all “minimal or no waste heat” conditions when a surgeon was added to the environment. For FAW with heat “on”, there is a second effect due to vented “waste heat” that must be considered: flow boundary stabilization²⁹. The velocity of the laminar airflow is greatly reduced in the vicinity of any rigid body (actually, zero at the surface), thus, the space between the surgeon’s body and operating table experiences a significant reduction in downward laminar flow velocity. The reduced downward velocity of the laminar airflow in this space is then overcome by the buoyancy of the vented waste heat, which is able to

rise into the surgical site. As evidence of this phenomenon, the combination of FAW vented “waste heat” and the presence of a surgeon resulted in a 48.6% tracer penetration of the laminar flow. In other words, approximately $\frac{1}{2}$ of the air immediately over the surgical site came from below the operating table, even though the surgical site was protected by a properly function laminar ventilation system operating at 0.3 m/s.

The final objective of this experiment was to determine if the airflow reaching the surgical site from below the operating table was composed of: 1) the vented waste heat and air exiting the FAW coverlet; and/or 2) the resident air near the floor. In our experiment, the FAW airflow entering the coverlet was filtered by an in-line HEPA filter and verified to be tracer free. Therefore, the tracer content of the air detected at the surgical site suggests that the FAW vented waste heat mixed with resident tracer-laden air near the floor and conveyed it towards the surgical site. We are not aware that it has ever been previously demonstrated how thermal sources, in a properly functioning laminar ventilation system, can mobilize significant quantities of resident floor air towards the surgical site.

Research assessing the effects of thermals, such as surgical lamp or anesthesia equipment waste heat, on laminar ventilation performance has found these effects to be minor¹⁷. Given that the heat release from surgical lamps occurs in an open laminar flow field, it is not surprising to find that the heat is quickly diluted and, thus, of minimal importance. Further, anesthesia equipment generates less waste heat than FAW¹⁸. In contrast, FAW use generates a large quantity of vented waste heat that is often released in a sheltered area under the operating table where it cannot be swept away by the laminar flow field.

The detection of resident floor air at the surgical site also entertains the possibility that FAW use may contribute to microbial contaminant mobilization from high risk areas. Prior research assessing FAW use and SSI risk has primarily focused on assessing the design of FAW blowers in regards to preventing contamination emissions in the effluent airflow¹¹⁻¹⁵. These studies routinely identify inadequate intake filtration performance as contributing to internal contamination build-up within FAW blowers and the consequent

emission of contaminants in the effluent airflow. As a solution to the problem, these studies suggest the implementation of a distal hose end HEPA filter. However, the results of this study suggest that even the release of contamination-free vented waste heat would still reduce laminar ventilation performance and may contribute to SSI risk. As such, further research is recommended to characterize how the use of FAW affects the mobilization of resident, not FAW generated, contaminants and whether this mobilization elevates the risks of SSI. Further, the relevance of such research may be heightened for surgeries involving the implantation of prosthetic joints, where the risks of SSI due to airborne contaminants increases exponentially^{30,31}.

Conclusion

This study assessed the effects of two comparably effective patient warming systems, FAW and conductive fabric blankets, on laminar ventilation performance. The results showed that FAW use significantly disrupts laminar ventilation performance. In contrast, conductive fabric blankets were shown to have no effect on laminar ventilation performance. This study also demonstrates that FAW vented “waste heat” can mobilize resident floor air upwards and into the surgical site above the operating table. Further, if the resident floor air is contaminant laden, this process may also convey these contaminants upwards and into the surgical site. Until the SSI risks resulting from FAW ventilation disruption can be evaluated, the use of air-free patient warming alternatives is recommended for contamination sensitive procedures.

Table 1. Background characteristics of laminar flow laboratory experimental environment.

Under-Table Tracer Concentration, mean (LCLM ; UCLM) [Particles $\geq 0.3 \mu\text{m}/\text{m}^3$]	
Day 1	52,181 (50,778 ; 53,584)
Day 2	49,872 (48,190 ; 51,555)
Day 3	55,356 (54,671 ; 56,042)
Pooled Average	52,398 (51,225 ; 53,571)
Forced Air Warming Blower Distal Airflow Tracer Concentration, mean (LCLM ; UCLM) [Particles $\geq 0.3 \mu\text{m}/\text{m}^3$]	
Day 3	208 (140 ; 284)
Laminar Flow Temperature Uniformity, mean (LCLM ; UCLM) [$^{\circ}\text{C}$]	
Day 1	21.0 (n/a*)
Day 2	20.5 (n/a*)
Day 3	20.5 (n/a*)
Laminar Flow Velocity Uniformity, mean (LCLM ; UCLM) [m/s]	
Day 1	0.3 (n/a*)
Day 2	0.3 (n/a*)
Day 3	0.3 (n/a*)

* no variation existed at time of measure across air plenum; LCLM, lower 95% confidence interval of mean; UCLM, upper 95% confidence interval of mean.

Table 2. Significance of ANOVA model fixed effects.

ANOVA Main Effects, <i>P</i>_value	
Surgeon (present or absent)	<0.001
Warming modality (forced air or conductive fabric)	<0.001
Controller heat setting (on or off)	<0.001
ANOVA Interactions, <i>P</i>_value	
Surgeon X warming modality	<0.001
Surgeon X controller heat setting	<0.001
Warming modality X controller heat setting	<0.001
Warming modality X controller heat setting X Surgeon	<0.001

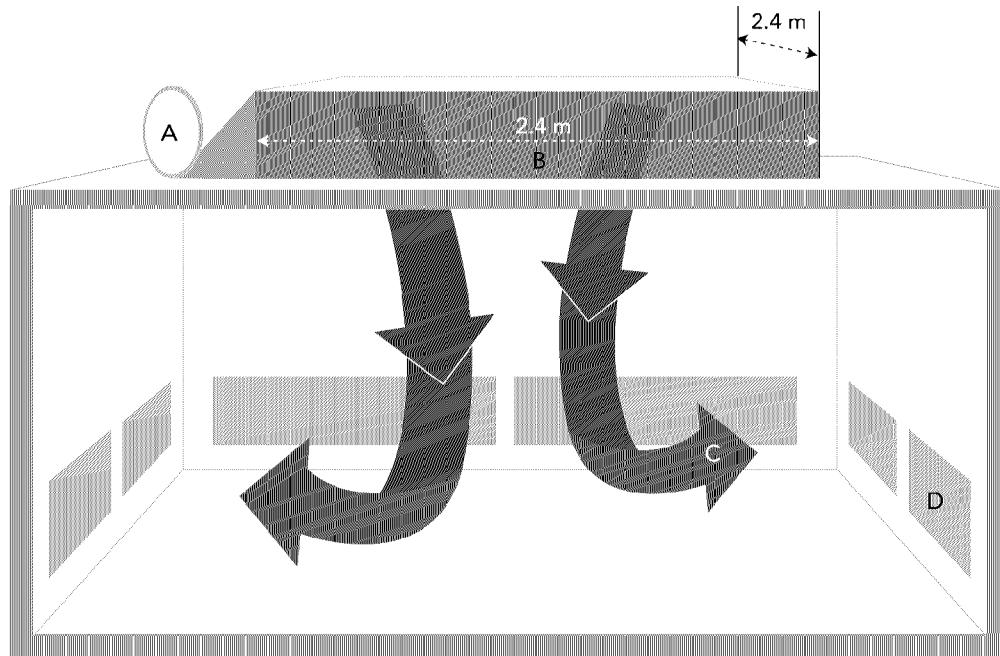


Figure 1: Laminar flow laboratory, having an HVAC ventilation blower (A) that pressurizes an air distribution plenum (B). The pressurized airflow enters the laboratory through the lower plenum surface and is filtered as it passes through a layer of HEPA filtration media. The filtered airflow (C) enters the laboratory in a downward fashion at a uniform velocity of 0.3 m/s. Waste airflow is exhausted through floor level return grates (D).

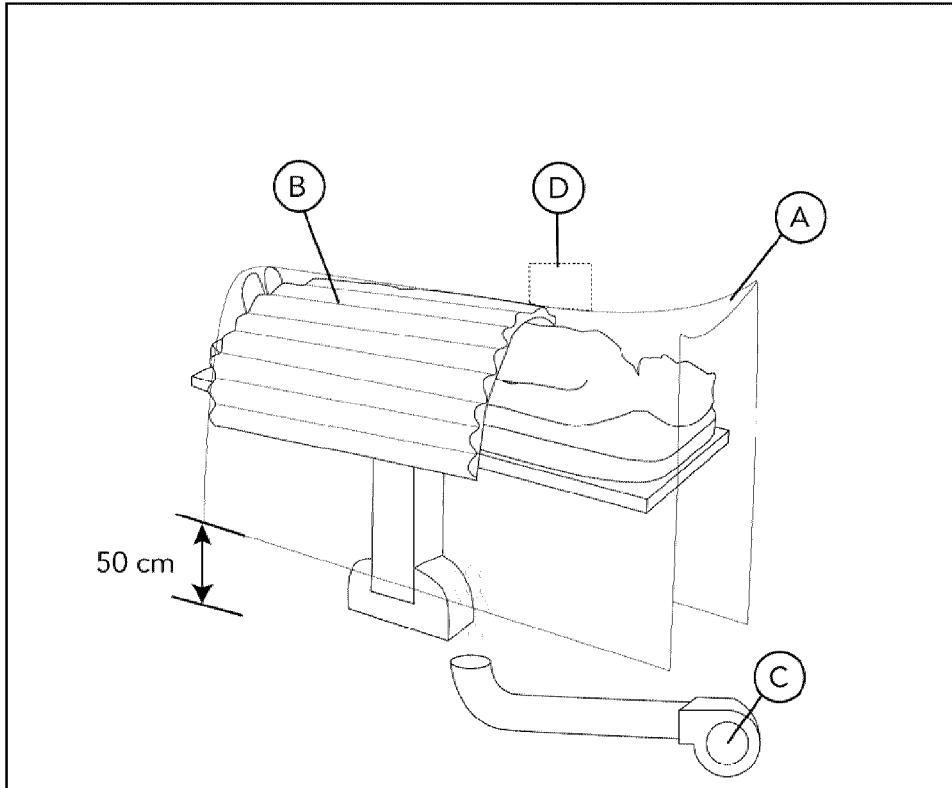


Figure 2: Experimental setup in center of laminar flow laboratory with adult mannequin in the supine position, showing: (A) surgical draping; (B) experimental warming treatment (conducting fabric blanket or forced air warming); (C) blower conveying tobacco tracer particle under the operating table; and (D) surgical site particle sampling location.

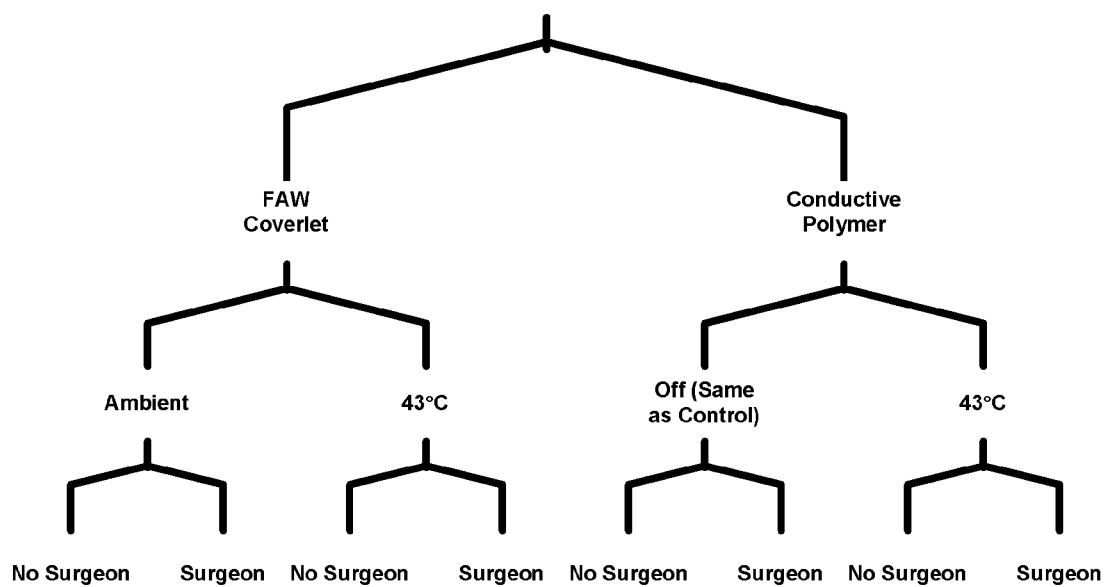


Figure 3: Full factorial experimental design.

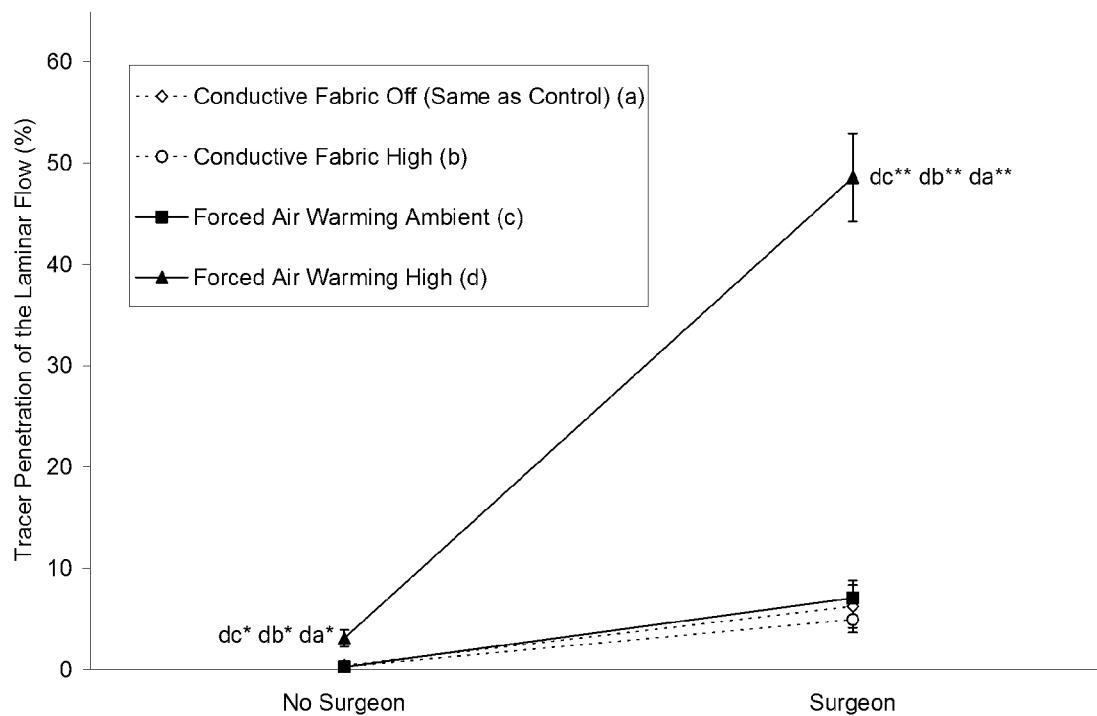


Figure 4: Mean treatment effects (\pm standard error of mean) for tracer penetration of the laminar flow. Significant pair wise differences identified for experiments with no surgeon present and experiments having a surgeon present. * $P<0.05$ and ** $P<0.01$ identify the family significance level of pair wise differences.

References

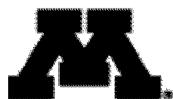
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Exhibit

AA



Christopher Nachtsheim <nacht001@umn.edu>

RE: Conversation last week

2 messages

Mark <malbrecht@augbiomed.com>
To: robinhumble29@gmail.com
Cc: Chris Nachtsheim <nacht001@umn.edu>

Wed, Mar 31, 2010 at 10:35 AM

That will be fine on friday. I will need to call in from the University of Minnesota. I will be in a meeting with my phd advisor, but he is a part of the current manuscript and I'm sure would like to join in on the call.

Let me know what number to call
-mark

-----Original Message-----

From: robinhumble29@googlemail.com [mailto:robinhumble29@googlemail.com]
Sent: Wednesday, March 31, 2010 4:42 AM
To: Mr Mike Reed; Mark Albrecht; Scott Augustine
Cc: Randy Benham; Andreas Deibel
Subject: Re: Conversation last week

Mark
How does 5pm UK time, 11am Minn. work.
Robin
Sent using BlackBerryR from Orange

-----Original Message-----

From: "Reed Mike (Northumbria Health Care NHS Trust)" <mike.reed@nhs.net>
Date: Wed, 31 Mar 2010 09:40:57
To: robinhumble29@gmail.com<robinhumble29@gmail.com>; Mark
Albrecht<malbrecht@augbiomed.com>; Scott Augustine<saugustine@augbiomed.com>
Cc: Randy Benham<rbenham@augbiomed.com>; Andreas
Deibel<adeibel@augbiomed.com>
Subject: RE: Conversation last week

5-6 best for me. I have a 6 pm meeting.

-----Original Message-----

From: robinhumble29@googlemail.com [mailto:robinhumble29@googlemail.com]
Sent: 31 March 2010 09:33
To: Reed Mike (Northumbria Health Care NHS Trust); Mark Albrecht; Scott
Augustine
Cc: Randy Benham; Andreas Deibel
Subject: Re: Conversation last week

Its good for me Mike, it would probably be best for the team in the US, if we could make this after 5pm, how does that sound?

Regards
Robin

Sent using BlackBerry(r) from Orange

-----Original Message-----

From: "Reed Mike (Northumbria Health Care NHS Trust)" <mike.reed@nhs.net>
 Date: Wed, 31 Mar 2010 06:07:52
 To: Mark<malbrecht@augbiomed.com>;
 robinhumble29@gmail.com<robinhumble29@gmail.com>; 'Scott
 Augustine'<saugustine@augbiomed.com>
 Cc: 'Randy Benham'<rbenham@augbiomed.com>; 'Andreas
 Deibel'<adeibel@augbiomed.com>
 Subject: RE: Conversation last week

Unfortunately I have a three session days this week and my trainee is away
 (who normally does all the work!).

I could probably have a telecon at 5pm UK time on Thursday but Friday is
 strangely much more convenient as it is a holiday - I can read/review the
 paper and have time to discuss it properly. Is anyone able to meet Friday
 afternoon UK time?

Mike

-----Original Message-----

From: Mark [mailto:malbrecht@augbiomed.com]
 Sent: 30 March 2010 17:09
 To: robinhumble29@gmail.com; 'Scott Augustine'; Reed Mike (Northumbria
 Health Care NHS Trust)
 Cc: 'Randy Benham'; 'Andreas Deibel'
 Subject: RE: Conversation last week

Ok, how about this. Lets use a Thursday meeting to review, with mike, the
 current laminar flow manuscript and answer any questions/concerns he may
 have. Then, let's set up a second meeting for Monday or Tuesday to cover a
 drafted protocol that should be completed by then.

What do you think?

-----Original Message-----

From: robinhumble29@googlemail.com [mailto:robinhumble29@googlemail.com]
 Sent: Tuesday, March 30, 2010 11:01 AM
 To: Mark Albrecht; Scott Augustine; Mr Mike Reed
 Cc: Randy Benham; Andreas Deibel
 Subject: Re: Conversation last week

Mark

This is great, remember that we use a different voltage on devices, we may
 need a transformer to use a 110 volt machine as we use 210/220 Its a Holiday
 here Friday, what about Thursday?

Regards

Robin

Sent using BlackBerryR from Orange

-----Original Message-----

From: "Mark" <malbrecht@augbiomed.com>
 Date: Tue, 30 Mar 2010 10:40:02
 To: <robinhumble29@gmail.com>; 'Scott Augustine'<saugustine@augbiomed.com>;
 'Reed Mike (Northumbria Health Care NHS Trust)'<mike.reed@nhs.net>
 Cc: 'Randy Benham'<rbenham@augbiomed.com>; Andreas
 Deibel<adeibel@augbiomed.com>

Subject: RE: Conversation last week

Robin,

I'm planning on sending Andreas that week to assist you in the data collection and provide help following a drafted protocol. We are working to create the sampling protocol draft for you and mike to review and add input to this week. We will also be providing a particle tracer generator and the bubble machine (should have it by then). I've been in our flow lab the last couple of days getting things de-risked. A conference call would be great. Propose a time. I'd suggest late this week for I could have a protocol together by then.

-mark

-----Original Message-----

From: Robin Humble [mailto:robinhumble29@googlemail.com]
Sent: Tuesday, March 30, 2010 10:28 AM
To: 'Scott Augustine'; 'Reed Mike (Northumbria Health Care NHS Trust)';
'Mark'
Cc: 'Randy Benham'
Subject: FW: Conversation last week

Dear Mike,

Please see confirmation from Mary at Vanguard regarding access to their Laminar Flow theatre April 24th and 25th.

I think we need to start to put together everything that we will need for the weekend, including Bair Huggers ect. How would you like to manage this, I have copied Scott and Mark Albrecht in the US to see what help they can give us, perhaps we should organise a conference call regarding this.

Please let me know if you have any questions.

Regards

Robin

Robin Humble

+44 7802 662727 (Mobile)

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-----Original Message-----

From: Mary Smallbone [mailto:MarySmallbone@vanguardhealthcare.co.uk]
Sent: 30 March 2010 16:13

To: 'robinhumble29@gmail.com'
Subject: Re: Conversation last week

Hi Robin

Thank you for your email and voice message I hope you are feeling better

We are planning to use Ipswich as the venue I have organised for Scott Horsley - senior theatre manager and Ian Balaam - maintenance engineer to be present they will open and close the unit and also they will be able to alter the temperature and air flows if required

The address of where the unit is

PCT Treatment Centre

Walker Close

Ipswich

Suffolk

IP3 8LY

We will be charging you as discussed so please can you let me know who you want who and where to send the invoice to

I will send an email to Scott and Ian following this one so that they can answer your laminar flow questions

Best wishes

Mary
Mary Smallbone
Sales and Operations Director

t: 01452 651882
m: 07771 851913

www.vanguardhealthcare.co.uk
Vanguard Healthcare Solutions Ltd.
Unit 1411 Charlton Court
Gloucester Business Park
Gloucester GL3 4AE

----- Original Message -----

From: Robin Humble <robinhumble29@googlemail.com>
To: Mary Smallbone
Sent: Tue Mar 30 09:52:14 2010
Subject: Conversation last week

Hi Mary,

Sorry I missed your call on Friday, in fact I have been laid low with some type of virus, but am back today and would like to continue our conversation regarding the Mobile Theatre in Ipswich. The days that I have provisionally booked in my diary are the 24/25th April, are these still good for you?

It would help us if we could obtain some specs regarding the Laminar flow in the theatre we will be using in order to be able to work up some of our calculations. I think that there will be three or four of us working on that weekend, one, Mike Reed is a Consultant Orthopaedic Surgeon from Northumbria, the other Professor Leaper from UHL, one of our Research technicians and myself.

You mentioned that you would have a couple of technicians on site, is that still the case, it would really help us, of course we will pay whatever we need to.

If it helps to talk by phone please let me know when this is convenient and I can call, assuming your number is still 07771 851913.

Warm regards

Robin

Robin Humble

+44 7525 226284 (Mobile)

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Robin Humble

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www.connectingforhealth.nhs.uk/nhsmail

Robin Humble <robinhumble29@googlemail.com>

Reply-To: robinhumble29@gmail.com

To: Mark <malbrecht@augbiomed.com>

Cc: Chris Nachtsheim <nacht001@umn.edu>

Wed, Mar 31, 2010 at 11:22 AM

Mark this is the dial in at 5pm UK time

+44 844 873 60 60

Pass key 56059

Please pass this on to anyone else from the US who plans to join the call, including Scott, AD etc..

Robin Humble

+44 7802 662727 (Mobile)

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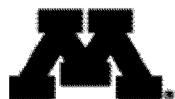
We do not accept any liability for any virus infection and/or external compromise of security in relation to transmissions by email.

-----Original Message-----

[Quoted text hidden]

Exhibit

BB



Christopher Nachtshelm <nacht001@umn.edu>

Publication Factory Continues

1 message

Mark <malbrecht@augbiomed.com>

Fri, Jul 9, 2010 at 3:44 PM

To: "Reed Mike (Northumbria Health Care NHS Trust)" <mike.reed@nhs.net>, Paul McGovern <pdmcgovern@gmail.com>

Cc: Scott Augustine <saugustine@augbiomed.com>, Andreas Deibel <adeibel@augbiomed.com>, Keith Leland <kleland@augbiomed.com>, rhumble@augbiomed.com, Christopher Nachtshelm <nacht001@umn.edu>

Paul and Mike,

At this point in time we have 3 completed manuscripts that are ready to be submitted for publication that you are both authors on:

1) An Evaluation Of Filtration Adequacy And Airborne Contamination Emissions From Next Generation Forced Air Warming Blowers. Target Journal: British Journal of Bone and Joint Surgery

2) Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Conventional (non-laminar, positive pressure) Operating Room Ventilation Disruption. Target Journal: US Annals or Archives of Surgery

3) Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Laminar Operating Room Ventilation Disruption. Target Journal: Undecided. This is the most complete piece of work on laminar flow disruption and should go to a top tier journal.

I've already sent both of you articles 1 & 2; article 3 is a new one and, arguably, the best of the three. When I'm in the UK next week I'd like to plan a time (the week of July 19th through 26th) for us to get together, agree on reviews, and submit these articles to 3 appropriate journals. I'd be willing to come up to Northumbria for these purposes.

Also, Dr Andrew Legg has invited you guys to Sheffield hospital the weekend of July 17th and 18th to help with the research effort there. If you are interested the company would be willing to cover your hotel and expenses. Let me know and I'll work to book arrangements. Also, I'm available to conduct further research in Northumbria the dates July 19th -26th. I have the equipment available for your use on those dates. Maybe we could brainstorm some interesting

research ideas.

I'll be available via e-mail this weekend.

Thanks

-Mark

P.S. Paul, I'll work to get some charts together for the 2 studies you sent to me that we can, hopefully, discuss in person.

Mark Albrecht

Augustine Biomedical & Design

6581 City West Parkway

Eden Prairie MN 55344

PH 952-465-3511

3 attachments

 [Manuscript_European_7-07_tracked.doc](#)
526K

 [Conventional_Vent_Manuscript_7-2.doc](#)
299K

 [Manuscript_Laminar_7-9.doc](#)
355K

Exhibit

CC

Redacted

From: Reed Mike (NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST - NE29 8NH) [mailto:mike.reed@nhs.net]
Sent: Friday, December 02, 2011 1:25 AM
To: Patrick Morgan; Bob Gorman; Mark Heller; CHENDRI1@Fairview.org; Liza and Jim Arendt; belan001@umn.edu
Subject: Re Infection Control with Bair Hugger

All

Sorry about the tardy response. I have attached the data that shows what happened since we wrote the paper and splits it between hips and knees - it's about another 400 cases. I have left the idiots guide that our statistician put on for me - I hope that helps!

You will see the effect is present for knees (0.6 vv 1.6%) as well as hips (1.3 vv 5.5%). The effect has been sustained.

I cannot really explain why we had such a difference in hip/knee infection rates. This was obviously a great source of concern to us. The effect of the warming method is present for both op types though. We now use conductive fabric warming (CFW) for both hips and knees (in fact all surgery in the hospital now, as it is cheaper).

Disclosures / Industry

In early 2009 our department did some microbiology work to see if we could culture bacteria around the table with FAW. Augustine (Hot Dog) sponsored this

work (£5K). It didn't show anything and was rejected by the British Hip Society. None of the authors received any personal income from that.

Augustine provided the clever bubble machine for this experiment in the JBJS. It didn't cost our unit anything (apart from our time) and no money changed hands. Scott Augustine bought me a pizza at the British Hip Society earlier this year. Regrettably (!) I have no shares in Hot Dog, or futures in Bair Hugger. In truth I have considered that but feel this message is so important I wanted it out without conflict.

I was present at the experiments (I'm the surgeon in the video) and I am infection lead in our hospital - I'm convinced by the data.

Mark Albrecht is the brainy one and he is a research student who is having his way through your uni paid, at least in part, by Augustine. I am happy with the data and analysis though. As you are so close you could probably get him in to demo this effect in your OR?

I am coming through your town in June as an ABC fellow. Perhaps we could talk it through?

Mike

From: Mike Reed <mike.reed@nhs.net<mailto:mike.reed@nhs.net>>
Date: Thu, 24 Nov 2011 06:43:48 +0000
To: Edward Cheng <cheng002@umn.edu<mailto:cheng002@umn.edu>>, Liza and Jim Arendt <arend001@umn.edu<mailto:arend001@umn.edu>>, "belan001@umn.edu<mailto:belan001@umn.edu>" <belan001@umn.edu<mailto:belan001@umn.edu>>
Cc: Patrick Morgan <morga050@umn.edu<mailto:morga050@umn.edu>>, Bob Gorman <drbobg@comcast.net<mailto:drbobg@comcast.net>>, Mark Heller <markheller@tcomm.com<mailto:markheller@tcomm.com>>, "CHENDRI1@Fairview.org<mailto:CHENDRI1@Fairview.org>" <CHENDRI1@Fairview.org<mailto:CHENDRI1@Fairview.org>>
Subject: Re: Infection Control with Bair Hugger

Morning. These are all fair questions. I am pulling some data on this (on what has happened since paper submission) and hopefully will reply more fully over the weekend, including disclosures.

Thank you very much for your interest in the paper.

Mike

From: Edward Cheng <cheng002@umn.edu<mailto:cheng002@umn.edu>>
Date: Sun, 20 Nov 2011 23:53:38 +0000
To: Liza and Jim Arendt <arend001@umn.edu<mailto:arend001@umn.edu>>, "belan001@umn.edu<mailto:belan001@umn.edu>" <belan001@umn.edu<mailto:belan001@umn.edu>>, Fax Felton <mike.reed@email.com<mailto:mike.reed@email.com>>

Cc: Patrick Morgan <morga050@umn.edu<mailto:morga050@umn.edu>>, Bob Gorman <drbobg@comcast.net<mailto:drbobg@comcast.net>>, Mark Heller <markheller@tcomm.com<mailto:markheller@tcomm.com>>, "CHENDRI1@Fairview.org<mailto:CHENDRI1@Fairview.org>" <CHENDRI1@Fairview.org<mailto:CHENDRI1@Fairview.org>>
Subject: FW: Infection Control with Bair Hugger

Liza,

Very interesting, I had never thought of this issue. I did read the article and they cite usage of the Bair hugger as compared to the conductive fabric blanket. Both are made in Eden Prairie in companies started by Scott Augustine, MD, anesthesiologist originally from twin cities.

It's only one paper but there probably is scant info on this topic. I don't know the implications of switching to the conductive fabric for warming but it seems worth investigating. Perhaps you'd be willing to do so?

Kumar / Mr Reed,
As a co-author of this paper,

- 1) do you know if the difference in infection % between forced air vs conductive fabric is statistically significant for hip replacement alone?
...knee replacement alone?
- 2) can you explain why knees had a much higher infection % compared to hips? As you know the opposite has been shown in prior studies. I'd presume some of those studies used a bair hugger. From your data, one might argue for the usage of a bair hugger when doing TKA's.
- 3) could you provide clarification of any perceived/potential conflict of interests?
- 4) Also, was industry involved in any way?

thanks

~~~~~  
Edward Y. Cheng, M.D.  
Mairs Family Professor  
Department of Orthopaedic Surgery, University of Minnesota  
2512 South 7th Street, R200  
Minneapolis, Minnesota 55455  
612.273.7951, 612.273.7987 fax  
www.ortho.umn.edu<http://www.ortho.umn.edu>  
www.sarcoma.umn.edu<http://www.sarcoma.umn.edu>  
www.umjointreplacement.umn.edu<http://www.umjointreplacement.umn.edu>  
~~~~~

From: Elizabeth A. Arendt, M.D. [mailto:arend001@umn.edu]
Sent: Saturday, November 19, 2011 4:30 PM
To: Edward Cheng
Cc: Karlen, Emily K
Subject: FW: Infection Control

Isn't this what the bear hugger is?
Should we change?

=====

Elizabeth A. Arendt, M.D.
Professor, Dept. of Orthopaedic Surgery
University of Minnesota
2512 So. 7th Street, Suite R200
Minneapolis MN 55454
Ph: 612-273-8059
FAX: 612-273-7959
e-mail: arend001@umn.edu<mailto:arend001@umn.edu>
Web: www.sportsdoc.umn.edu<http://www.sportsdoc.umn.edu/>

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60 day deep infection rates before and after moving to CFW.pdf

Exhibit

DD

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Redacted

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-----Original Message-----

From: saugustine@augbiomed.com

Redacted

Sent: 2016-10-04 7:55:54 PM

Subject: Personal

Redacted

I hope all is well with you. Augustine Temperature Management (ATM) is raising investment funds, and we're doing it without venture capital—that's why I'm contacting my friends as well as anesthesia and surgical colleagues. Please feel free to forward this email to any of your colleagues who might be interested.

I hope you don't find this offensive, but rather see it as an invitation to participate in an entrepreneurial company with an incredible value proposition.

We're working to close-out the Series B round of financing, which would make all new investors the lowest risk "last money in" on a huge opportunity in the patient warming market. We believe that forced-air warming (FAW) is soon-to-be obsolete. Hot-water systems were rejected by clinicians long ago. With air and water out of the OR, *electric warming is the only choice*. Our air-free HotDog® warming is the only effective electric warming system available in the US today. This is truly a "once in a lifetime" opportunity for any entrepreneur.

Most surgeons and anesthesiologists have heard that there are ten (10) studies showing that the waste heat and air from FAW contaminates the sterile surgical

field and the OR.¹⁻¹⁰ Most are also aware that this airborne contamination has been linked to 75% of joint implant infections in two studies.^{1,11} You may not have heard, however, that there are over 800 lawsuits against 3M/Bair Hugger for implant infections. The Multi-District Litigation has been certified by the Federal Court, and over 20,000 lawsuits are possible.

Finally, you may not have heard that the Healthcare Infection Control Practices Advisory Committee (HICPAC) of the Centers for Disease Control and Prevention (CDC) has recently issued a warning against using *any* equipment that blows air in the operating room:

“Nothing that blows air should be in an operating theater, if possible.”

and

“...it is important not to blow air in the operating theater.”¹²

An even stronger warning was published in the CDCs *Emerging Infectious Diseases Journal*:

“Until more detailed evidence is available regarding this issue...devices that generate drafts should be banned from the operating room.”¹³

My opinion: No product that has been linked by published research to contamination of the sterile field and catastrophic infections, identified by the CDC as an infection risk, is the subject of a warning from the CDC not to be used in the OR and is the target of mass tort litigation can survive in the medical marketplace.

Clearly air-free, electric warming is the future since it has none of the contamination problems caused by FAW. HotDog warming is the *only* comprehensive air-free system available and has a proven track record of success with over 4 million patient uses. HotDog’s value proposition extends beyond patient safety:

- *More effective:* More effective than FAW and alternatives because it warms from above *and* below simultaneously.
- *Lower cost:* Saves 20-70% over FAW warming costs.
- *Ergonomic:* No waste heat annoying the surgeons, no noise, no cumbersome hose and no blanket loft.

To finance what we see as an explosive growth opportunity, we are raising an *additional* \$4M to the \$6.8M already raised in this Series B investment round. Not only is this the “last money in” for this round, but also will most likely be the last investment opportunity in the HotDog/ATM franchise.

I am proud to say that we do not have any venture capital invested in ATM because we have had hundreds of physician investors in our projects over the years. The new Jumpstart Our Business Startups legislation (the JOBS Act) allows all of our colleagues to participate, thus, this is our version of “crowdfunding”— except it’s an equity investment. I hope you join us as an

investor (\$20,000 minimum). Investments will be accepted on a “first-come first-serve basis.” You are an expert in this market and should certainly recognize the opportunity ahead of us. As an expert we also welcome your input on both products and strategy. Together we can achieve great returns while significantly improving patient care.

I have attached the Executive Summary of this offering for your review. If you have questions and/or would like the full Private Placement Memorandum (PPM) and Subscription Agreement for review, please contact us:

Scott Augustine MD
CEO
saugustine@augbiomed.com
953-465-3502

Brent Augustine
President
baugustine@hotdog-usa.com
952-746-1721

Warm regards,
Scott

Scott D. Augustine MD
CEO
Augustine Temperature Management, LLC
Augustine Biomedical + Design, LLC
6581 City West Parkway
Eden Prairie, MN 55344
saugustine@augbiomed.com
AugustineBiomedical.com
HotDog-USA.com

952-465-3502 (O)
612-710-1277 (m)

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References:

1. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone and Joint Surg-Br.* 2011;93(11):1537-1544.
2. Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012;67:244-249.
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6. Scherrer M. Hygiene and room climate in the operating room. *Min Invas Ther & Allied Tech* 2003;12(6):293-299.
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10. Hamilton KR. Skin Contamination Following use of a Forced Air Warming Device. Presentation at the Annual Meeting of the AANA, Washington DC, 2016
11. Augustine SD. Forced-air warming is associated with periprosthetic total joint replacement infections. Submitted for publication.
12. Healthcare Infection Control Practices Advisory Committee, Division of Healthcare Quality Promotion, CDC, pg-27, Nov. 5-6, 2015.
13. Sommerstein R, Ruegg C, Kohler P, Bloomberg G, Kuster SP, Sax H. Transmission of *Mycobacterium chimaera* from Heater-Cooler Units during Cardiac Surgery despite an Ultraclean Air Ventilation System. *Emerging Infectious Diseases* (CDC). 2016;22(6):1008-1013

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EE

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From: Randy Benham [<mailto:rbenham@augbiomed.com>]
Sent: Wednesday, October 19, 2016 3:24 PM
To: Micah Hines
Cc: Mary Young; Jerry Blackwell; Ben Hulse; JMC@ciresiconlin.com; MVC@ciresiconlin.com; bgordon@levinlaw.com; Genevieve Zimmerman
Subject: Re: Request for meet and confer

Ms. Hines:

I am writing in response to your letter dated October 17.

As for the meet and confer: your letter speaks of a "final attempt to meet and confer," suggesting that there have been previous unsuccessful attempts. That is not accurate. In any case, I presume you are proposing a telephone call, as that is what you have preferred in the past. If so, I could be available briefly tomorrow at 2:00. If that won't work for you, Monday at 2:00 is also available.

To my knowledge, the privilege log is complete.

Given that virtually all of the documents I have produced have been electronic, it is clear that I have searched my client's electronic files. I am unaware, however, that I have an obligation to respond to the extra-judicial interrogatories contained in your letter. If I am incorrect, please provide case or FRCP citations.

No article entitled "Forced-air warming is associated with periprosthetic total joint replacement infections" has been published. It is unlikely, I believe, that the Court will allow your client to review articles containing your competitor's research prior to publication.

Before I begin blocking Dr. Augustine's schedule for a day of deposition, could you please confirm that your opposing counsel has agreed to the dates you propose? Assuming that they have, however, December 13 appears to be preliminarily acceptable.

Regarding the differences regarding which you intend to file a motion to compel, could you please provide me a detailed list in advance of the filing?

Thanks,

Randy

J. Randall Benham

General Counsel
Augustine Temperature Management LLC
6581 City West Parkway
Eden Prairie, MN 55344

From: Micah Hines <mhines@blackwellburke.com>

Date: Monday, October 17, 2016 at 10:35 PM

To: Randy Benham <rbenham@augbiomed.com>

Cc: Mary Young <myoung@blackwellburke.com>, Jerry Blackwell <blackwell@blackwellburke.com>, Ben Hulse <BHulse@blackwellburke.com>, "JMC@ciresiconlin.com" <JMC@ciresiconlin.com>, "MVC@ciresiconlin.com" <MVC@ciresiconlin.com>, "bgordon@levinlaw.com" <bgordon@levinlaw.com>, Genevieve Zimmerman <gzimmerman@meshbesher.com>

Subject: Request for meet and confer

Please see attached.

Best,
Micah



431 South 7th Street
Suite 2500
Minneapolis, MN 55415

Micah Hines
Blackwell Burke P.A.

612.343.3284 Direct
612.343.3205 Fax

mhines@blackwellburke.com

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Exhibit

FF

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From: Randy Benham [<mailto:rbenham@augbiomed.com>]

Sent: Thursday, October 27, 2016 2:43 PM

To: Micah Hines

Cc: Jerry Blackwell; Mary Young; Ben Hulse; JMC@ciresiconlin.com; MVC@ciresiconlin.com; bgordon@lewinlaw.com; gzimmerman@meshbesher.com; Ahmann, Bridget M.

Subject: Re: Request for information

Ms. Hines,

It is my understanding that the confidentiality of reports filed in the Medwatch system are protected by federal privacy laws. Although I have not done a great deal of legal research on this topic, I did find an article by former FDA Commissioner David Kessler informative. You may read it at <http://www.fda.gov/downloads/Safety/MedWatch/UCM201419.pdf> Apparently the FDA has intervened several times regarding this issue.

Assuming my understanding of the law is correct, it would not be appropriate for me to respond to your question.

Since you have raised the issue, however, I must question why your client has not filed Medwatch reports on the 800-900 reports of injury that it has received via the service of legal documents. The filings certainly initiated the 30-day period within which our client was obligated to file. I just checked the Medwatch website, however, and your client apparently has not filed a single report.

Randy

J. Randall Benham

General Counsel
Augustine Temperature Management LLC
6581 City West Parkway
Eden Prairie, MN 55344

From: Micah Hines <mhines@blackwellburke.com>

Date: Wednesday, October 26, 2016 at 7:11 PM

To: Randy Benham <rbenham@augbiomed.com>

Cc: Jerry Blackwell <blackwell@blackwellburke.com>, Mary Young <myoung@blackwellburke.com>, Ben Hulse <BHulse@blackwellburke.com>, "JMC@ciresiconlin.com" <JMC@ciresiconlin.com>, "MVC@ciresiconlin.com" <MVC@ciresiconlin.com>, "bgordon@lewinlaw.com" <bgordon@lewinlaw.com>, "gzimmerman@meshbesher.com" <gzimmerman@meshbesher.com>, "Bridget.Ahmann@FaegreBD.com" <Bridget.Ahmann@FaegreBD.com>

Subject: Request for information

Mr. Benham,

During our meet and confers on October 20 and October 24, we asked whether you produced all documents in response to Request 14. Please respond to our questions below by close of business tomorrow.

Please confirm that you have produced all non-privileged documents in the possession, custody or control of Dr. Augustine or the subpoenaed entities that relate to MDRs sent to the FDA concerning the Bair Hugger system. This includes (but is not limited to) drafts of MDRs and correspondence concerning the drafting, editing, or submission of MDRs.

Please also confirm that to the extent you have withheld any such documents on the basis of privilege, those documents are listed on your privilege log or will be listed in a supplement to your privilege log by October 31.

Best,
Micah

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

AFFIDAVIT OF DAVID W. HODGES

1. My name is David Hodges. I am over the age 18 and competent to make this affidavit. I am a partner at the law firm Kennedy Hodges, LLP. I am one of the attorneys representing the Plaintiff in the instant matter. The facts contained herein are within my personal knowledge and are true and correct.

2. On July 6, 2009, Kennedy Hodges, LLP was retained by Dr. Scott Augustine to provide legal representation to his company, Augustine Biomedical + Design, LLC.

3. As a result, there exist written communications between Kennedy Hodges and Augustine Biomedical; however, these communications were made in confidence between a client to his attorney for the purpose of obtaining legal advice.

4. Moreover, these communications involve confidential client matters, including core trade secrets of Augustine Biomedical. These communications also include the mental impressions of Kennedy Hodges in providing legal advice to the company.

5. To my knowledge, there have been no other non-privileged communications between Dr. Augustine and counsel for the Plaintiff in this matter.

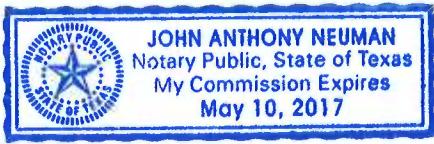
FURTHER YOUR AFFIANT SAYETH NOT

David W. Hodges
David W. Hodges

Exhibit

GG

Sworn to and subscribed before me by David W. Hodges on MAY 6, 2015.





Notary Public

Exhibit

HH

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

TOMMY WALTON,)
Plaintiff,)
v.)
3M COMPANY; ARIZANT)
HEALTHCARE, INC.; AND)
ROBERT PRESTERA)
Defendants.)

Civil Action No.
4:13-cv-01164

**PLAINTIFF'S RESPONSE TO DEFENDANTS' MOTION
TO COMPEL PLAINTIFF'S RESPONSES TO DISCOVERY**

COMES NOW, Plaintiff Tommy Walton, and files this Response to Defendants' Motion to Compel Plaintiff's Responses to Discovery (Doc. 103). Defendants' Motion should be denied because the only responsive communications are protected by the attorney-client privilege.

I.

Defendants' Motion seeks all communications between Plaintiff's counsel and Dr. Scott Augustine.¹ Dr. Augustine is the original inventor of the 3M Bair Hugger warming blanket. Dr. Augustine left Defendants' employment in 2003. Shortly after leaving the company, Dr. Augustine began to publicize information regarding an infection risk

¹ Defendants' Motion also seeks information relating to the expected subject matter of Dr. Augustine's testimony. Plaintiff has supplemented his response to Interrogatory No. 11 to provide a full description. Accordingly, the only remaining issue in Defendants' Motion relates to communications.

caused by the device he invented. As might be expected, 3M's response to Dr. Augustine's public criticism of the Bair Hugger was hostile. Moreover, in the intervening years, Dr. Augustine began to market a new alternative patient warming system, placing him in direct competition with one of the world's largest corporations. With the relationship between Dr. Augustine and 3M growing increasingly tense, the possibility of legal or regulatory retaliation increased. Dr. Augustine had already once been involved in litigation with his former employer, and he feared further legal disputes.

II.

As such, on July 6, 2009, years before the instant litigation, Dr. Augustine retained Kennedy Hodges, LLP to represent his company, Augustine Biomedical + Design, LLC.² Kennedy Hodges is also one of the law firms representing Plaintiff in this matter. Accordingly, while there exist communications between Kennedy Hodges and Dr. Augustine, they were "made in confidence by a client to his attorney for the purpose of obtaining legal advice." *United States v. Pipkins*, 528 F.2d 559, 562 (5th Cir. 1976). Therefore, they are protected by the attorney-client privilege.

III.

When this litigation began in 2013, Plaintiff's counsel anticipated designating Dr. Augustine as an unpaid consulting expert so they could discuss discovery matters with him. However, during the parties' negotiation of the Protective Order of Confidentiality, 3M did not consent to Dr. Augustine reviewing discovery materials since they contain 3M trade secrets. Thus, Plaintiff's counsel agreed to de-designate Dr. Augustine and

² See Exhibit 1, Affidavit of David Hodges.

stated they would not be talking to Dr. Augustine about the discovery to be produced in this case nor showing him any documents. Plaintiff's counsel repeated this assurance on the record.³ Accordingly, there are no communications of any kind between Dr. Augustine and Plaintiff's counsel relating to the discovery record in this case or relating to the particular facts involving Mr. Walton's surgery and injury. Moreover, 3M is incorrect in stating that Dr. Augustine has been using information about this case provided by Plaintiff's counsel "in his campaign against the Bair Hugger."⁴ It appears that Dr. Augustine's public statements regarding this lawsuit contain information he has independently secured from the Court's public file. Finally, Dr. Augustine's affidavit, submitted in response to 3M's Motion to Quash the deposition of Gary Maharaj, came about as the result of a phone call between Dr. Augustine and Plaintiff's counsel. That affidavit lists personal meetings Dr. Augustine had with Mr. Maharaj in 2008 and 2009. There have been no other non-privileged responsive communications.

IV.

The attorney-client privilege is designed "to encourage clients to make full disclosure to their attorneys." *Fisher v. United States*, 425 U.S. 391, 403 (1976). "[T]he attorney-client privilege protects communications made in confidence by a client to his lawyer for the purpose of obtaining legal advice. The privilege also protects communications from a lawyer to the client." *Hodges, Grant & Kaufmann v. United States*, 768 F.2d 719, 720-21 (5th Cir.1985). "An attorney-client communication is also

³ See Doc. 103, Ex. K.

⁴ See Doc. 103, at p. 6

protected under the Sixth Amendment if it is intended to remain confidential and was made under such circumstances that it was reasonably expected and understood to be confidential.” *United States v. Nelson*, 732 F.3d 504, 518 (5th Cir. 2013). All of these elements apply to communications made between Kennedy Hodges and Dr. Augustine, as the communications relate to legal advice and confidential client matters which should not be disclosed. Disclosure of the communications would also threaten the core trade secrets of Augustine Biomedical + Design, as well as the mental impressions of Kennedy Hodges in providing legal advice to the company. 3M cannot be allowed to intrude on these attorney-client communications, especially as the communications are related to a long existing dispute between Dr. Augustine and 3M.

V.

Because the only responsive communications were made in connection with an attorney-client relationship pre-dating this lawsuit, they are protected by privilege and must not be disclosed. Therefore, Plaintiff prays this Court denies Defendants’ Motion to Compel.

Respectfully submitted,

KENNEDY HODGES, LLP

/s/ Gabriel A. Assaad
David W. Hodges
State Bar No. 00796765
Federal Bar No. 20460
dhodges@kennedyhodges.com
Gabriel A. Assaad
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Houston, Texas 77002
Telephone: (713) 221-8300
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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Motion was served via the ECF System for the Southern District of Texas on May 6, 2015.

By: /s/ Gabriel A. Assaad
Gabriel A. Assaad

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TOMMY WALTON,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.
)	4:13-cv-01164
3M COMPANY; ARIZANT)	
HEALTHCARE, INC.; AND)	
ROBERT PRESTERA)	
)	
Defendants.)	

AFFIDAVIT OF DAVID W. HODGES

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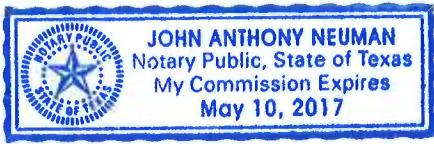
5. To my knowledge, there have been no other non-privileged communications between Dr. Augustine and counsel for the Plaintiff in this matter.

FURTHER YOUR AFFIANT SAYETH NOT



David W. Hodges

Sworn to and subscribed before me by David W. Hodges on MAY 6, 2015.





Notary Public

Exhibit

II

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

TOMMY WALTON,

§

Plaintiff,

§

v.

§

CIVIL ACTION NO. H-13-1164

3M COMPANY, ARIZANT HEALTHCARE,
INC., and ROBERT PRESTERA,

§

Defendants.

§

ORDER

Before the Magistrate Judge upon referral from the District Judge is Defendant 3M Company's Motion to Compel Plaintiff's Responses to Discovery (Document No. 103). In that motion, Defendant seeks an Order compelling Plaintiff to provide a response to Defendant's "Supplemental Interrogatory No. 1", and produce documents responsive to Request for Production No. 1, both of which seek information about Plaintiff's contacts and communications with Dr. Scott Augustine. In response to the motion, Plaintiff and his counsel represent that they have had no contact or communications with Dr. Augustine relative to this case, other than a telephone call between Plaintiff's counsel and Dr. Augustine about meetings Dr. Augustine had with Mr. Maharaj in 2008 and 2009. As for any other communications and contacts, Plaintiff's counsel has advised that his law firm, Kennedy Hodges, LLC, represented Dr. Augustine's company, Augustine Biomedical + Design, LLC, in 2009, and maintains that any communications and contacts related to that representation are privileged.

Having considered Defendant's Motion to Compel, Plaintiff's response in opposition, the disclosure of the contacts Plaintiff and his counsel have had with Dr. Augustine related to this case,

and the fact that Dr. Augustine is not a consulting or testifying expert for Plaintiff in this case, it is

ORDERED that Defendant's Motion to Compel (Document No. 103) is DENIED.

Defendant may, of course, seek discovery directly from Dr. Augustine, who has been identified by Plaintiff as a fact witness, through a deposition and/or a subpoena.

Signed at Houston, Texas, this 19th day of May, 2015.



FRANCES H. STACY
UNITED STATES MAGISTRATE JUDGE

Exhibit

JJ

Redacted

From: Randy Benham <rbenham@augbiomed.com>

Date: June 28, 2016 at 3:36:06 PM CDT

To: Ben Hulse <BHulse@blackwellburke.com>

Cc: "Jan M. Conlin (JMC@ciresiconlin.com)" <JMC@ciresiconlin.com>, MVC@CiresiConlin.com" <MVC@CiresiConlin.com>, "Ben Gordon bgordon@levinlaw.com" <bgordon@levinlaw.com> <bgordon@levinlaw.com>, Genevieve Zimmerman <gzimmerman@meshbisher.com>, Jerry Blackwell <blackwell@blackwellburke.com>, Mary Young <myoung@blackwellburke.com>

Subject: Re: More detailed reaction to Document Request -4

Mr. Hulse:

This email, I believe, will conclude my more detailed responses to your client's document demands. Preliminarily, however, I would like to point out a typographical error that I discovered in my June 17 initial objections to your discovery: The statement "The following General Objections apply to Requests 1-15..." should have referred to Requests 1-58.

Rather than grouping the responses below in purely numerical order, I have organized them by the nature of the response. I hope this is helpful.

Response Group 1

Request No 5— General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 5. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on

behalf of my clients that there are no responsive documents relating to the Bair Hugger warming system or to forced-air warming generally in the possession or control of my clients.

Request No 10--General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 10. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents relating to the Bair Hugger warming system, to forced-air warming generally or to the HotDog system in the possession or control of my clients.

Request No 15--General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 15. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents relating to the Bair Hugger warming system or to forced-air warming generally in the possession or control of my clients. Given that Magistrate Noel previously ordered production of documents responsive to a request that was similar, although not identical, to Request No 15, my client will review it files and, if additional responsive documents are discovered, supplement the original response appropriately.

Request No 21-- General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 21. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents in the possession or control of my clients.

Request No 22-- General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 22. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents in the possession or control of my clients.

Request No 23-- General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 23. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents in the possession or control of my clients.

Request No 24-- General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 24. Magistrate Noel previously ordered creation and production of a privilege log responsive to a request that was similar, although not identical, to Request No 24. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no additional responsive documents in the possession or control of my clients.

Request No 25-- General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 25. Magistrate Noel previously ordered creation and production of a privilege log responsive to a request that was similar, although not identical, to Request No 25. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no additional responsive documents in the possession or control of my clients.

Request No 26-- General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 26. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents in the possession or control of my clients.

Request No 27-- General Objections 1, 2, 3, 4 and 6 apply specifically to Request No 27. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on

behalf of my clients that there are no responsive documents in the possession or control of my clients.

Request No 28— General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 28. Magistrate Noel previously ordered creation and production of a privilege log responsive to a request that was could reasonably be read to be encompassed by Request No 28. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no additional responsive documents, whether privileged or unprivileged, in the possession or control of my clients.

Request No 29— General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 29. Magistrate Noel previously ordered creation and production of a privilege log responsive to a request that was could reasonably be read to be encompassed by Request No 29. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no additional responsive documents, whether privileged or unprivileged, in the possession or control of my clients.

Request No 30— General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 30. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents in the possession or control of my clients.

Request No 33— General Objections 1, 2, 3, 4 and 6 apply specifically to Request No 33. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents in the possession or control of my clients.

Request No 42— General Objections 1, 2, 3, 4 and 6 apply specifically to Request No 42. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents in the possession or control of my clients.

Response Group 2

In general, this group contains documents demands for which I can discern no proper and rational basis of inquiry—other than general curiosity and a desire to obtain information about a competitor.

Request No 4— General Objections 1, 2, 3, 4 and 6 apply specifically to Request No 4.

Request No 6— General Objections 1, 2, 3, 4, 5 and 6 apply specifically to Request No 6. Without limitation of such objections, the continuing medical education presentation to which Request No 6 obliquely refers has already been produced and/or is easily found on the Internet.

Request No 7— General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 7.

Request No 8— General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 8.

Request No 9— General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 9.

Request No 11— General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 11.

Request No 12--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 12.

Request No 13--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 13.

Request No 14--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 14.

Request No 16--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 16.

Request No 17--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 17.

Request No 18--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 18.

Request No 19--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 19.

Request No 20--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 20.

Request No 31--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 31.

Request No 32--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 32.

Request No 34--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 34.

Request No 36--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 36.

Request No 37--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 37.

Request No 38--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 38.

Request No 39--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 39.

Request No 40--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 40.

Request No 41--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 41.

Request No 43--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 43.

Request No 44--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 44.

Request No 46--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 46.

Request No 48--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 48.

Request No 49--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 49.

Request No 51--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 51.

Request No 52--General Objections 1, 2, 3, 4, 6 and 7 apply specifically to Request No 52.

Mr. Hulse, although I have done my best to respond individually to each of your numerous document demands, it is possible that I have misstated (or even totally missed) one or more. It is my intention to review each of the 58 responses tomorrow and make any corrections that are required.

Randy

J. Randall Benham

General Counsel
Augustine Temperature Management LLC
6581 City West Parkway
Eden Prairie, MN 55344

From: Randy Benham <rbenham@augbiomed.com>
Date: Wednesday, June 22, 2016 at 2:10 PM
To: Ben Hulse <BHulse@blackwellburke.com>
Cc: "Jan M. Conlin (JMC@ciresiconlin.com)" <JMC@ciresiconlin.com>, "MVC@CiresiConlin.com" <MVC@CiresiConlin.com>, "Ben Gordon (bgordon@levinlaw.com) (bgordon@levinlaw.com)" <bgordon@levinlaw.com>, Genevieve Zimmerman <gzimmerman@meshbesher.com>, Jerry Blackwell <blackwell@blackwellburke.com>, Mary Young <myoung@blackwellburke.com>
Subject: More detailed reaction to Document Request -3

Mr. Hulse:

My efforts continue:

Request No 53— General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 53. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that all such documents have already been produced.

Request No 54— General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 54. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that all such documents have already been produced.

Request No 55— General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 55. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that all such documents have already been produced.

Request No 56— General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 56. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents relating to the Bair Hugger warming system or to forced-air warming generally in the possession or control of my clients.

Request No 57— General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 57. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents in the possession or control of my clients.

Request No 58--General Objections 1, 2, 3, 4, and 6 apply specifically to Request No 58. To avoid unnecessary conflict, but without waiver of such objections, however, I can represent on behalf of my clients that there are no responsive documents in the possession or control of my clients.

Randy

J. Randall Benham

General Counsel
Augustine Temperature Management LLC
6581 City West Parkway
Eden Prairie, MN 55344

From: Randy Benham <rbenham@augbiomed.com>
Date: Tuesday, June 21, 2016 at 12:30 PM
To: Ben Hulse <BHulse@blackwellburke.com>
Subject: More detailed reaction to Document Request -2

To make review of my first set of comments easier, I have attached them below.

Other requests (or portions of requests) to which I have no objections include the following:

Request No 35-- In response to a previous request, all videos and still photography related to Bair Hugger forced-air warming were produced. Although Request No 35 is much more detailed than the previous request, it is not actually broader. In any case, all such videos and photographs have already been produced.

Request No 45--Although I believe any such documents were produced previously, I will review my client's files and produce documents appropriately.

Request No 47-- I will review my client's files and produce documents appropriately.

Request No 50-- To the best of my knowledge, all such documents have already been produced.

Mr. Hulse, I intend to continue making progress on these responses daily—although I am sure you understand that it is not my only responsibility, and that it may take some time.

Randy

J. Randall Benham

General Counsel
Augustine Temperature Management LLC

6581 City West Parkway
Eden Prairie, MN 55344

From: Randy Benham <rbenham@augbiomed.com>
Date: Monday, June 20, 2016 at 3:41 PM
To: Ben Hulse <BHulse@blackwellburke.com>
Subject: More detailed reaction to Document Request -1

Mr. Hulse,

The purpose of this email is to attempt to narrow our potential dispute regarding the non-party document discovery served by your clients. First, however, I would like to confirm that the document requests served on each of the entities are identical. I have been unable to identify differences, but I don't want to inadvertently overlook some slight variation among the demands—and I am sure you have no desire to be tricky.

Second, I would like to confirm that you are providing copies of our correspondence to attorneys representing the plaintiffs in the MDL. If you would prefer that I "cc" them directly, please provide the appropriate email addresses, and I will do so.

Finally, I have decided to send my comments as I am able, rather than wait until I have analyzed each of them. If I send nothing until I complete this project, there is some risk that you will question my diligence. I suggest that you not respond to my comments, however, until I have reacted to each of the requests. If we begin negotiating piecemeal, I will have no time to draft the initial responses.

There are some requests (or portions of requests) to which I have no objections:

Request No 1 — If such a document exists, it will be produced.

Request No 2— This document has already been produced.

Request No 3— This request is not substantively different from Request No 2, and the document has already been produced.

Request No 14— Magistrate Noel previously ordered that my clients should produce documents regarding communications to third parties about the risks of forced-air warming. Your list of potential recipients does not broaden the scope of Magistrate Noel's order—which encompassed all such communications. To the best of my knowledge, such documents were produced, subject to a confidentiality order. Any new documents came into being since that production will be identified and produced—again, subject to a confidentiality order. To the extent that Request No 14 demands documents unrelated to the safety of forced-air warming, the General Objections previously provided are specifically asserted.

Request No 15— The comments regarding Request No 14 apply to Request No 15 as well. To the best of my knowledge, however, there are no

additional documents to be produced that are response to this Request. Nevertheless, I will investigate.

Request No 18— This request seems to be encompassed by Request No 15, and the response is the same.

Request No 24— Magistrate Noel previously ordered that a privilege log be provided in response to a substantially identical request. Such log was, in fact, provided. To the best of my knowledge, there are no supplements.

Request No 29— See response to Request No 24.

Randy

J. Randall Benham

General Counsel
Augustine Temperature Management LLC
6581 City West Parkway
Eden Prairie, MN 55344

From: Randy Benham <rbenham@augbiomed.com>
Date: Friday, June 17, 2016 at 3:24 PM
To: Ben Hulse <BHulse@blackwellburke.com>
Subject: Re: In re Bair Hugger, MDL 2666 -- Subpoenas

Mr. Hulse,

The purpose of this email is to register objections on behalf of the numerous non-parties on which you have served subpoenas for the production of documents. Please consider this communication to be a timely objection to your client's demands as well as assertions of privilege and protection as provided for by FRCP 45. Such objections and assertions include those listed below.

The number and scope of your demands, Mr. Hulse, is overwhelming. Given the expansive definitions, the multiple subparts, and the number of non-parties involved, there are literally hundreds of document requests which must be considered. While it is my intention to respond in detail to each of the requests, I will need at least next week to do so.

In the meantime, I respectfully request that you reconsider the scope of your demands. Your discovery is largely unrelated to the issues involved in MDL 2666. Instead, you seek discovery as if 3M and my clients were involved in unfair competition litigation. We are not. Our clients are fierce competitors, but it is inappropriate for 3M to use MDL 266 as an excuse to gain competitive information about HotDog patient warming.

General Objections

The following General Objections apply to Requests 1-15 generally and to each Request specifically.

1. The demands are overly broad, vague and ambiguous.
2. The demands are unreasonable and oppressive.
3. The demands require disclosure of confidential and trade-secret documents and information.
4. The demands require disclosure of documents and information that is not relevant to the litigation under Rule 26.
5. The demands require disclosure of documents and information available from the discovering party itself or from public sources.
6. The demands require disclosure of documents and information the production of which would be unduly burdensome and expensive.
7. The demands require disclosure of documents and information that are privileged or otherwise protected from disclosure. To fully comply with FRCP 45(e)(2)(A) at this point would itself be unduly burdensome and expensive, but further elaboration will be forthcoming.

Sincerely,

Randy

J. Randall Benham

General Counsel
Augustine Temperature Management LLC
6581 City West Parkway
Eden Prairie, MN 55344

Exhibit

KK

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates to All Actions

**PLAINTIFFS' RESPONSES TO
DEFENDANTS' FIRST REQUESTS
FOR PRODUCTION OF DOCUMENTS TO
PLAINTIFFS**

INTRODUCTION

Plaintiffs have responded to these requests in the context of general discovery on causation and the Court's scheduling order. Plaintiffs' good faith notwithstanding, many of these requests could be construed as requesting information from individual plaintiffs and their attorneys in a manner inconsistent with MDL practice. Moreover, this Court, in keeping with usual MDL practice, has already considered and ordered Plaintiffs' Fact Sheets to be addressed and completed by Plaintiffs, following standard MDL practice where Plaintiff Fact Sheets typically take the place of other general written discovery. As such, Plaintiffs will provide individual fact discovery, fact sheets and other specific-causation information consistent with the Court's scheduling order.

OBJECTIONS AND RESPONSES TO REQUESTS FOR PRODUCTION

REQUEST NO. 1

Produce all Documents identified, referenced, used and/or relied upon in preparing Plaintiffs' Initial Disclosures re: General Causation.

RESPONSE:

Plaintiff asserts the work product privilege as this request specifically asks for what counsel relied upon in preparing Plaintiffs' Initial Disclosures, which necessarily implicates counsels' mental impressions in preparing those disclosures. Subject to the work product privilege, see all documents Defendants produced and the transcripts of depositions that were taken in *Walton v. 3M*, No. 4:13-cv-01164, pending in the United States District Court for the Southern District of Texas, and *Johnson v. 3M*, No. 2-14-cv-0204400-KHV-TJJ, pending in the United States District Court for the District of Kansas. Plaintiffs are gathering and will produce additional information responsive to this request, including literature, manuals, advertisements, articles, and the like.

REQUEST NO. 2

Produce all Documents and/or Communications identified, referenced, used and/or relied upon in preparing the allegations in the Master Complaint that relate to issues of general causation.

RESPONSE:

See Response to Request No. 1.

REQUEST NO. 3

Produce all Documents that relate to Your allegations that the Bair Hugger system was defectively manufactured or designed.

RESPONSE:

Plaintiff asserts the work product privilege as this request specifically asks for all documents counsel believes relate to Plaintiffs' claims, which necessarily implicates counsels' mental impressions. Subject to the work product privilege, see all documents defendants produced and the transcripts of depositions that were taken in *Walton v. 3M*, No. 4:13-cv-01164, pending in the United States District Court for the Southern District of Texas, and *Johnson v. 3M*, No. 2-14-cv-0204400-KHV-TJJ, pending in the United States District Court for the District of Kansas. Plaintiffs are gathering and will produce additional information responsive to this request, including literature, manuals, advertisements, articles, and the like.

REQUEST NO. 4

Produce all Documents and/or Communications sent by You or Your attorneys or that You or Your attorneys received from any entity, including but not limited to the following, that

concern, refer or relate in any way to the Bair Hugger system, conductive warming, and/or forced air warming:

- a. the Centers of Disease Control and Prevention
- b. Center for Devices and Radiological Health of the U.S. Food and Drug Administration
- c. U.S. Food and Drug Administration
- d. Surgical Care Improvement Project (SCIP)
- e. Royal College of Surgeons
- f. United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA)
- g. United States Department of Health and Human Services
- h. ECRI Institutes
- i. Health Canada
- j. National Health System (NHS)
- k. National Institute for Health and Care Excellence (NICE)

RESPONSE:

Plaintiffs object to the extent the request seeks information regarding all attorneys who represent any plaintiff in *In re Bair Hugger Forced Air Warming Products Liability Litig.*, MDL 15-2666, as over broad and unduly burdensome. Subject to that objection, no such communications exist from members of the Plaintiffs' Executive Committee.

REQUEST NO. 5

Produce all Documents and/or Communications relating to any MedWatch report, including but not limited to Form FDA 3500B, submitted to the U.S. Food and Drug Administration concerning the Bair Hugger system and/or Defendants.

RESPONSE:

Plaintiffs object to the extent the request seeks information regarding all attorneys who

represent any plaintiff in *In re Bair Hugger Forced Air Warming Products Liability Litig.*, MDL 15-2666, as over broad and unduly burdensome. Subject to that objection, no such communications exist from members of the Plaintiffs' Executive Committee.

REQUEST NO. 6

Produce all Documents and Communications sent by You or Your attorneys to, or that You or Your attorneys received from, any United States or foreign governmental agency or division thereof, including but not limited to, the Centers of Disease Control and Prevention, that concern, refer, or relate in any way to surgical site infection data and surgical site infection rates.

RESPONSE:

Plaintiffs object to the extent the request seeks information regarding all attorneys who represent any plaintiff in *In re Bair Hugger Forced Air Warming Products Liability Litig.*, MDL 15-2666, as over broad and unduly burdensome. Subject to that objection, no such communications exist from members of the Plaintiffs' Executive Committee.

REQUEST NO. 7

Produce all Documents relating to any conference (including any legal or medical conference), seminar, presentation, administrative hearing, or governmental hearing concerning whether the Bair Hugger system or forced air warming increases the risk of harm to patients.

RESPONSE:

Plaintiffs object and assert the attorney work product privilege to the extent the request seeks documents shared with counsel for individual plaintiffs with claims against Defendants related to injuries from the Bair Hugger device. Subject thereto, the information sought is equally available to Defendants and is therefore unduly burdensome to Plaintiffs. Additionally, Plaintiffs are producing documents relating to presentations made in seminars to audiences including both plaintiff and defense attorneys.

REQUEST NO. 8

Produce all peer-reviewed studies, including, but not limited to, epidemiological studies, on which You and/or Your attorneys rely in support of Your claims that the Bair Hugger system is capable of causing surgical site infections following orthopedic surgeries or any other type of

surgery.

RESPONSE:

Plaintiffs object as the materials sought are protected by the attorney work product and consulting expert privilege. Plaintiffs further object as the request is premature. Subject to the foregoing objections, Plaintiffs will produce responsive materials when testifying experts are designated pursuant to the Court's scheduling order. Further, see materials to be produced in response to Request No. 1.

REQUEST NO. 9

Produce all treatises, books, articles, reports, manuals or opinions which have been published in a professional, medical or scientific journal or other publication in the United States or any other country, upon which You base any of Your claims.

RESPONSE:

. See Response to Request No. 8.

REQUEST NO. 10

Produce all Documents and/or Communications sent by You or Your attorneys to, or that You or Your attorneys received from, medical and scientific journals concerning the publication or possible publication of any research concerning surgical site infections and forced air warming devices.

RESPONSE:

Plaintiffs object to the extent the request seeks information regarding all attorneys who represent any plaintiff in *In re Bair Hugger Forced Air Warming Products Liability Litig.*, MDL 15-2666, as over broad and unduly burdensome. Subject to that objection, no such communications exist from members of Plaintiffs' Executive Committee.

REQUEST NO. 11

Produce all inspection reports, examination reports, testing reports, test results and/or test protocols relating to any tests, analyses, studies, trials, or experiments that You, Your attorneys, or anyone acting on Your behalf has performed on or with the Bair Hugger system or any other

medical device used for patient warming.

RESPONSE:

Plaintiffs object as the materials sought are protected by the attorney work product and consulting expert privilege. Plaintiffs further object as the request is premature. Subject to the foregoing objections, Plaintiffs will produce responsive materials when testifying experts are designated pursuant to the Court's scheduling order.

REQUEST NO. 12

For all inspection reports, examination reports, testing reports, test results and/or test protocols responsive to Request No. 11: produce all underlying data and Documents reflecting related communications, funding, payments, materials supplies, design, conduct, and analysis.

RESPONSE:

See Response to Request No. 11.

REQUEST NO. 13

Produce all demonstrative Documents and materials including diagrams, pictorial representations, sketches, chronologies, animations, models, videotapes, photographs, recordings, if any, relating to Your allegations that the Bair Hugger system increases the risk of harm to patients.

RESPONSE:

Plaintiffs object as the materials sought are protected by the attorney work product and consulting expert privilege. Plaintiffs further object as the request is premature. Subject to the foregoing objections, Plaintiffs will produce responsive materials when testifying experts are designated pursuant to the Court's scheduling order.

REQUEST NO. 14

Produce all Documents, including Communications, that You contend constitute any admission of wrongdoing, proof of liability, or negligence by 3M Company or Arizant Healthcare.

RESPONSE:

Plaintiffs object to the request as premature as discovery is on-going. Subject to that objection, see Response to Request No. 1. See also all Litigation Consulting Agreements (LCAs) Defendants entered into with former employees, as well as all hearing transcripts and orders regarding the propriety of the LCAs issued by the Honorable Kenneth M. Hoyt in *Walton v. 3M*, No. 4:13-cv-01164, pending in the United States District Court for the Southern District of Texas, Houston Division.

REQUEST NO. 15

Produce all Documents, and/or Communications to or from, any Health Care Provider or Health Care Facility with whom You or Your attorneys have consulted regarding the safety of the Bair Hugger system, including but not limited to correspondence, written statements, affidavits, brochures, medical literature and the like.

RESPONSE:

See Response to Request No. 11.

REQUEST NO. 16

Produce all Documents and/or Communications sent to or received from any Health Care Provider or Health Care Facility regarding the Bair Hugger system, forced air warming and/or the Defendants including but not limited to correspondence, written statements, affidavits, brochures, medical literature and the like.

RESPONSE:

Plaintiffs object as the materials sought are protected by the attorney work product and consulting expert privileges. To the extent the request seeks medical records of individual plaintiffs, the request is overbroad and does not relate to issues of general causation. Plaintiffs further object as the request is premature. Subject to the foregoing objections, Plaintiffs will produce responsive materials when testifying experts are designated pursuant to the Court's scheduling order.

REQUEST NO. 17

Produce all Documents and/or Communications sent to or received from any Health Care Provider or Health Care Facility regarding forced air warming, including but not limited to

correspondence, written statements, affidavits, brochures, medical literature and the like.

RESPONSE:

See Response to Request No. 16.

REQUEST NO. 18

Produce all Documents and/or Communications to, and from, any Health Care Provider or Health Care Facility with whom You or Your attorneys have consulted who has criticized the Bair Hugger system.

RESPONSE:

Plaintiffs object as the materials sought are protected by the attorney work product and consulting expert privilege.

REQUEST NO. 19

Produce all Documents and/or Communications to, and from, any Health Care Provider or Health Care Facility with whom You or Your attorneys have consulted who has praised any aspect of the Bair Hugger system.

RESPONSE:

Plaintiffs object as the materials sought are protected by the attorney work product and consulting expert privilege.

REQUEST NO. 20

Produce all Documents and/or Communications to, and from, any Health Care Provider or Health Care Facility with whom You or Your attorneys have consulted who has criticized forced air warming.

RESPONSE:

Plaintiffs object as the materials sought are protected by the attorney work product and consulting expert privilege.

REQUEST NO. 21

Produce all Documents and/or Communications to, and from, any Health Care Provider or Health Care Facility with whom You or Your attorneys have consulted who has praised forced air warming.

RESPONSE:

Plaintiffs object as the materials sought are protected by the attorney work product and consulting expert privilege.

REQUEST NO. 22

Produce all Documents relating to complaints or concerns about the Bair Hugger system, including but not limited to Communications received from and sent to HotDog users, Health Care Providers, and Health Care Facilities.

RESPONSE:

Plaintiffs assert the attorney client, attorney work product, and consulting expert privileges; subject thereto, see documents produced in response to Request No. 1. No other non-privileged documents are responsive that are not equally available to Defendants.

REQUEST NO. 23

Produce all Documents and/or Communications that concern or relate to in any way, any alternative design, warning, manufacturing, distribution, or supply that You contend 3M Company or Arizant Healthcare could have adopted for the Bair Hugger system.

RESPONSE:

Plaintiffs object as the request is overbroad and the materials sought are protected by the attorney work product and consulting expert privileges. Plaintiffs further object as the request is premature. Subject to the foregoing objections, Plaintiffs will produce responsive materials when testifying experts are designated pursuant to the Court's scheduling order.

REQUEST NO. 24

Produce all Documents regarding forced air warming products, other than the Bair Hugger warming system, including but not limited to the Mistral forced air warming device.

RESPONSE:

Plaintiffs object as the request is overbroad and fails to identify the documents sought with reasonable particularity. Further, the information sought is equally available to defendants and therefore is unduly burdensome. Finally, “all documents regarding forced air warming products” is vague and overly broad.

REQUEST NO. 25

Produce all Documents relating or referring to any communication between You or Your attorneys and the following entities, and/or their owners, officers, employees, agents, affiliates or representatives, including but not limited to Dr. Scott Augustine:

- a. Augustine Medical
- b. Augustine Temperature Management
- c. Augustine Team
- d. Augustine Biomedical + Design
- e. HotDog USA, LLC
- f. HotDog International

RESPONSE:

Plaintiffs object to the extent the request seeks information regarding all attorneys who represent any plaintiff in *In re Bair Hugger Forced Air Warming Products Liability Litig.*, MDL 15-2666, as overbroad and unduly burdensome. Subject to those objections, Plaintiffs assert the attorney client and work product privileges. No non-privileged responsive documents exist.

REQUEST NO. 26

Produce all Documents sent to or received from the following individuals relating to the Bair Hugger Warming System, forced air warming, conductive warming, the HotDog, convective

warming, Defendants and/or the Bair Hugger litigation:

- a. Mark Albrecht
- b. Kiran Dasari
- c. Robert Gauthier
- d. Kumar Belani
- e. Christopher Natscheim
- f. Mark Litchy
- g. Mike Reed
- h. Paul McGovern
- i. Andrew Legg
- j. David Leaper
- k. Andrew Hamer
- l. Mark Harper

RESPONSE:

See Response to Request No. 4.

REQUEST NO. 27

Produce all Documents relating to any communications between You or Your attorneys and any person, including but not limited to current or former patients of any Healthcare Provider regarding the Bair Hugger warming system, forced air warming, the HotDog and/or SSIs.

RESPONSE:

Plaintiffs assert the attorney client, work product, and consulting expert privileges. Further, communications with testifying experts are specifically excluded from discovery by Fed. R. Civ. P. 26(b)(4)(C). Plaintiffs also object to the extent the request seeks information regarding all attorneys who represent any plaintiff in *In re Bair Hugger Forced Air Warming Products Liability Litig.*, MDL 15-2666, as overbroad and unduly burdensome. Subject to the privileges and objections, no such documents exist from

members of Plaintiffs' Executive Committee.

REQUEST NO. 28

Produce all Documents and/or Communications, written or recorded statements, reports or memoranda, and/or transcribed statements, reports, or memoranda from any person concerning any facts relating to Your allegations that the Bair Hugger system increases the risk of harm to patients, specifically including but not limited to, any statement provided by 3M Company or Arizant Healthcare or by any of their agents, representatives, employees, or former employees, pertaining to the facts underlying or allegations concerning general causation contained in the Master Complaint.

RESPONSE:

See Response to Request No. 3.

REQUEST NO. 29

Produce all Documents or materials, including but not limited to all written, recorded and/or transcribed statements, which record, evidence or reference any correspondence or communications between You and 3M Company or Arizant Healthcare regarding the Bair Hugger system or any allegation contained in the Master Complaint.

RESPONSE:

Plaintiffs object to the extent the request seeks communications between the attorneys to the litigations, as the information is equally available to Defendants. Plaintiff assert the work product privilege to the extent the request seeks counsel's internal memoranda regarding communications with Defendants. Plaintiffs further object to the extent the request seeks information regarding all attorneys who represent any plaintiff in *In re Bair Hugger Forced Air Warming Products Liability Litig.*, MDL 15-2666, as overbroad and unduly burdensome. Subject to the privileges and objections, no such documents exist from members of Plaintiffs' Executive Committee.

REQUEST NO. 30

Produce all Documents relating to the following individuals, including but not limited to

documents relating to their July 16, 2008 Affidavit Under Oath, the Bair Hugger warming system, forced air warming, filters, the HotDog, Defendants, the Bair Hugger warming system litigation, and/or any payment, gift, gratuity or compensation, whether contemplated, discussed, promised, provided, considered or exchanged between You or Your attorneys and the following individuals:

- a. Keith Leland
- b. Randy Arnold
- c. Scott Entenman
- d. Mark Albrecht
- e. Andreas Diebel

RESPONSE:

Plaintiffs object to the extent the request seeks information regarding all attorneys who represent any plaintiff in *In re Bair Hugger Forced Air Warming Products Liability Litig.*, MDL 15-2666, as overbroad and unduly burdensome. Subject to the objections, no such documents exist from members of Plaintiffs' Executive Committee.

REQUEST NO. 31

Produce all Documents relating to the following videos, including but not limited to documents relating to test conditions, results, test protocols, all aspects of the ventilation system of the operating room or entity and its performance, equipment used, adjustments made to the devices, devices used, persons present, persons involved, data, photographs, video, footage and manuscripts:

- a. "Forced-air Patient Warming Causes Vortex that Deposits Contaminants within Surgical Field"
- b. "Airborne Contamination in the Operating Room"
- c. "Forced-Air Warming Destroys Laminar Air-flow"

d. Any videos posted to <http://heat-rises.blogspot.com>, hotdogwarming.com, orthopaedicinfectionadvisory.org, stopsurgicalinfections.org

RESPONSE:

Plaintiffs object as they have no responsive documents other than what is equally available to Defendants in the public domain.

REQUEST NO. 32

Produce all Documents, including documents sent to or received from any person or entity, relating to Scott Augustine's service as a witness, possible role as a witness, disclosure as a witness and/or subsequent removal as a witness in the Bair Hugger warming system litigation.

RESPONSE:

Plaintiffs assert the work product privilege. Subject thereto, see all correspondence, pleadings, and productions from the *Walton* and *Johnson* cases referenced in Response to Request No. 1.

REQUEST NO. 33

Produce all Documents and/or Communications, including correspondence or other written records, provided by You or Your attorneys to any witness in this litigation.

RESPONSE:

Plaintiffs assert the consulting expert privilege. Communications with testifying experts are specifically excluded from discovery by Fed. R. Civ. P. 26(b)(4)(C). Plaintiffs further object to the extent the request seeks information regarding all attorneys who represent any plaintiff in *In re Bair Hugger Forced Air Warming Products Liability Litig.*, MDL 15-2666, as overbroad and unduly burdensome. Subject to the privileges and objections, see exhibits to the deposition of Dr. Clyburn taken in the *Walton* matter.

REQUEST NO. 34

Produce all Documents sent to or received from any consultant relating to the Bair Hugger warming system, forced air warming, conductive warming, Defendants, performance and/or testing of the HotDog.

RESPONSE:

Plaintiffs assert the consulting expert privilege. Further, communications with testifying experts are specifically excluded from discovery by Fed. R. Civ. P. 26(b)(4)(C).

REQUEST NO. 35

Produce all Documents and/or Communications furnished by You or Your attorneys or contained in the files of any witness who has advised You or Your attorneys, whether or not specially retained for this litigation or for trial, concerning any matter in the Master Complaint, including but not limited to correspondence, facsimiles, retainer and fee agreements, and any invoices for services rendered.

RESPONSE:

See Response to Request No. 34.

REQUEST NO. 36

Produce all Documents (including but not limited to any reports, graphs, studies, notes, photographs, slides, or any other written memoranda) either prepared by or contained in the files of any experts who are expected to testify at the time of trial or any expert consultant who is not expected to be called as a witness at the time of trial but whose work product forms the basis, either in whole or in part, of the opinions of an expert who will be called as a witness at trial.

RESPONSE:

Plaintiffs object to the extent the request seeks communications with testifying experts and draft reports, as that material is specifically excluded from discovery. Plaintiffs further object as the request is premature. Subject to the foregoing objections, Plaintiffs will produce responsive materials when testifying experts are designated pursuant to the Court's scheduling order.

REQUEST NO. 37

Produce all Documents that You intend to offer as an exhibit at any trial, hearing, or other in-court proceeding in this matter.

RESPONSE:

Plaintiffs will comply with the Court's schedule order regarding the exchange of any exhibits.

Dated: July 1, 2016

CIRESI CONLIN L.L.P.

/s/ Michael V. Ciresi

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